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NO. 97-

IN THE

Supreme Court of the United States

OCTOBER TERM, 1997

BARBARA MITCHELL and GREGORY MITCHELL,
Petitioners,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Seventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In light of this Court's decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), holding that none of the plaintiffs' state-law tort claims was preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. 360c *et seq.*, did the court of appeals err in holding that all such claims are preempted here simply because the Food and Drug Administration had granted pre-market approval for the medical device alleged to have caused petitioners' injuries?

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Barbara Mitchell and Gregory Mitchell seek a writ of certiorari to challenge the Seventh Circuit's ruling that all of their state-law tort claims alleging injuries caused by a medical device are preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act.

This is not the first time that this case has been before this Court. On July 1, 1996, the Court granted certiorari, vacated a prior decision of the court of appeals, and remanded the case for reconsideration in light of *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996), which held that the state-law tort claims presented there were **not** preempted by the MDA. This case has returned because the Seventh Circuit reaffirmed its prior broad preemption ruling despite *Medtronic*.

This Court should grant review for two related reasons. **First**, the Court should resolve a split of authority in the federal and state appellate courts over the meaning of *Medtronic*. The lower courts are in sharp disagreement as to whether claims relating to medical devices that have undergone the MDA's pre-market approval ("PMA") process are preempted. Some courts have held that such claims come within *Medtronic*'s no-preemption holding, but others have held that they do not, because the device in *Medtronic* did not undergo PMA, but had been cleared for marketing under a different provision of the MDA. In large part, this deepening division concerns whether MDA preemption extends to common-law tort claims, such as those alleged by petitioners, that are based on "general state common-law requirements ... not specifically developed 'with respect to' medical devices." 116 S. Ct. at 2258. In ruling against petitioners, the court of appeals noted the divergence of appellate authority.

Second, the Court should grant review because a significant number of appellate courts, including the court below, have erroneously reaffirmed their broad pre-*Medtronic* interpretations

of the MDA's preemption provision, 21 U.S.C. 360k(a). These courts have failed to follow this Court's holding that claims based on state-law duties of general applicability are not preempted under section 360k(a) and have mistakenly concluded that PMA is a preemptive "requirement" under that section. *See Medtronic*, 116 S. Ct. at 2258.

OPINIONS BELOW

The opinion of the Court of Appeals for the Seventh Circuit on which review is sought is reported at 126 F.3d 902 (7th Cir. 1997), and is reproduced in the appendix at 1a. The opinion of the District Court for the Northern District of Indiana is reported at 870 F. Supp. 885 (N.D. Ind. 1994), and is reproduced in the appendix at 27a. The Seventh Circuit's pre-*Medtronic* opinion is reported at 67 F.3d 1268 (7th Cir. 1995), and is reproduced in the appendix at 53a. The decision of this Court granting certiorari, vacating the original decision of the court of appeals, and remanding the case in light of *Medtronic* is reported at 116 S. Ct. 2576 (1996), and is reproduced in the appendix at 88a.

JURISDICTION

The judgment of the court of appeals was entered on September 23, 1997. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTE AND REGULATION INVOLVED

21 U.S.C. 360k(a) provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or

continue in effect with respect to a device intended for human use any requirement—

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act [21 U.S.C. 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in

addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

STATEMENT OF THE CASE

In 1988, petitioner Barbara Mitchell received injections of a medical device called Zyderm, a brand of injectable bovine collagen marketed by respondent Collagen Corporation as a method to smooth out rough or damaged skin. Ms. Mitchell alleges that respondent's product caused her severe and debilitating autoimmune disease. This petition presents the question whether Ms. Mitchell may seek recovery for her injuries under Indiana common law, or whether, as respondent maintains, the MDA, enacted in 1976 to protect consumers from potentially dangerous medical devices, bars Ms. Mitchell's access to the tort system entirely. Part A below describes the structure of the MDA, and Part B briefly explains the initial proceedings in this case. In Part C, we consider this Court's decision in *Medtronic v. Lohr*, which interpreted the MDA's preemption provision and caused the Court to remand this case the first time certiorari was sought. Finally, in Part D, we describe the holding of the court of appeals currently under review.

A. The Medical Device Amendments.

The principal purpose of the MDA was to increase consumer protection by preventing the distribution of dangerous medical devices and providing a structure through which devices would reach the market. H.R. Rep. 853, 94th Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976)(codified at 21 U.S.C. 360c *et seq.*). Three components of this regulatory structure are relevant to this petition.

First, every medical device falls into one of three classes. In general, as health risks from a device increase, so does regulatory scrutiny under the MDA. H.R. Rep. 853, *supra* at 34; 21 U.S.C. 360c(a). Class I devices, such as band aids, are the least risky and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the Food and Drug Administration ("FDA"), the agency charged by Congress with implementing the MDA. *See id.* § 360c(a)(1)(A).

Class II devices are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). Thus, the FDA may subject them to "special controls," such as the agency's specific warning label for tampons. *See* 21 C.F.R. 801.430(c),(d)&(e).

Finally, class III devices—such as Zyderm or the pacemaker at issue in *Medtronic*—are those that, in theory, cannot be marketed until the FDA has found that the device presents a reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). This process is known as pre-market approval ("PMA"). *Id.* § 360e(b)(1)(A) However, if the FDA finds that a class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. 21 U.S.C. 360e(b)(1)(B), 360c(f)(1)(A).

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, in addition to the tampon warning label mentioned above, the FDA has required that hearing aids bear certain labels and that tampon absorbency be tested in a specific manner. *See* 21 C.F.R. 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirement for injectable

bovine collagen.

Third, the MDA contains a preemption provision, 21 U.S.C. 360k(a), which preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to" conflicting MDA "requirements." Under 21 U.S.C. 360k(b), the FDA has the authority to exempt from preemption certain state requirements that would otherwise be preempted. Thus, the FDA has issued regulations concerning the scope of MDA preemption, which reflect section 360k(a)'s narrow reach. *See generally* 21 C.F.R. Part 808; *see also Medtronic*, 116 S. Ct. at 2257 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation"). For instance, the regulations require that for an FDA requirement to have preemptive effect, it must establish a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. 808.1(d). Likewise, to be preempted, state-law requirements also must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates ... to other products in addition to devices." *Id.* § 808.1(d)(1).

B. Facts and Initial Proceedings.

In 1988, petitioner Barbara Mitchell received a series of injections of Zyderm. As indicated above, Zyderm is a brand of injectable bovine collagen marketed by respondent. Zyderm is a class III medical device for which respondent obtained FDA pre-market approval in 1981 (3a). After the injections, Ms. Mitchell became extremely ill and developed a debilitating autoimmune disorder. CA App., Complaint, Count I, ¶ 6.

Thereafter, Ms. Mitchell filed suit in Indiana state court seeking damages from respondent under Indiana common law for her permanent physical impairments, loss of life's enjoyment, pain and suffering, and past and future medical expenses. *Id.*

Count I, ¶ 12. She alleged that respondent was liable under theories of strict products liability and negligence, common-law fraud, misrepresentation, failure to warn, product mislabeling and misbranding, product adulteration, and breach of warranty. *Id.* Count I, ¶ 7, Count IV, ¶ 2. Ms. Mitchell's husband, Gregory, sought damages for loss of consortium. *Id.* Count III.

Respondent removed the case to the District Court for the Northern District of Indiana under 28 U.S.C. 1441(a) on the basis of diversity of citizenship, 28 U.S.C. 1332, and moved for summary judgment, arguing that all of the Mitchells' claims are preempted by the MDA (32a). The district court granted respondent's motion in its entirety, relying on pre-*Medtronic* decisions holding that the MDA broadly preempts state-law tort claims (52a). The Seventh Circuit affirmed (53a).

After the Seventh Circuit's original affirmance, petitioners sought review in this Court, which held the petition pending the outcome in *Medtronic*. Thereafter, it granted the petition, vacated the Seventh Circuit's ruling, and remanded for reconsideration in light of *Medtronic* (88a). Because of the importance of *Medtronic* to the issues before this Court, we now review that decision in some detail.

C. The Decision in *Medtronic v. Lohr*.

In *Medtronic*, plaintiff Lora Lohr brought suit under Florida law for damages resulting from an allegedly defective class III pacemaker component that the FDA had cleared for marketing under its "substantial equivalence" process. This Court held that none of Lohr's claims—based on defective design, defective manufacture, and failure to warn—was preempted by the MDA.

1. *The Majority Opinion.* The majority opinion contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all common-law claims against device manufacturers, *Medtronic*, 116 S.Ct. at 2251 (majority); *id.* at 2263-64 (O'Connor, J., concurring in part and

dissenting in part); (2) Lohr's design-defect claim was not preempted, because the FDA had not issued any design specifications for the device in question, *id.* at 2254-55 (majority); *id.* at 2263-64 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to" requirements imposed under the MDA or FDA regulations is not preempted. *Id.* at 2255-56 (majority); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, the Court also held that Lohr's manufacturing-defect and failure-to-warn claims were not preempted, even if they did more than merely seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 2257. The generality of the FDA's manufacturing and labeling regulations applicable to the pacemaker, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 2258.

Similarly, the Court noted that Lohr's common-law claims were not preempted because they were premised on general state-law duties that do not focus specifically on medical devices. Thus, the Court found, the general duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because of their generality, the majority held, such state-law claims are outside the prohibited category of

requirements "with respect to" specific devices, within the meaning of section 360k(a). *Id.*[1]

2. *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages suits. He therefore did not join the plurality opinion (*see supra* note 1) because he was not convinced that MDA preemption of common-law claims would be "rare." *Id.* at 2262. He joined fully, however, in the views set forth above and in Part V of the majority opinion, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements related to Lohr's claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulations, 21 C.F.R. 808.1(d), that amplify the meaning of section 360k(a)'s specificity requirement. 116 S. Ct. at 2260-61. He noted that the language of section 360k(a) reflected basic principles of conflict preemption, but found no conflict between any federal requirement and any of Lohr's claims. *Id.*

3. *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by the Chief Justice and Justices Scalia and Thomas. She stated that common-law claims can constitute "requirements" under section 360k(a). *Id.* at 2262-63. Although concurring with the majo[illegible] that Lohr's design-defect claim was not preempted, she [illegible]uld have held the

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[1] Speaking for a four-Justice plurality, the lead opinion also relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages actions. *Id.* at 2252 (distinguishing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)). The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's analysis, none of Lohr's claims was preempted. *Id.* at 2258-59.

manufacturing-defect and failure-to-warn claims preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 2264. She agreed with the majority that Lohr's manufacturing-defect and failure-to-warn claims were not preempted to the extent that they merely alleged violations of federal requirements. *Id.*

D. The Decision Below.

After remand from this Court in light of *Medtronic*, the court of appeals again held that petitioners' claims are preempted. In analyzing *Medtronic*, the Seventh Circuit reached two general conclusions. First, it held that the PMA process itself was a "specific" requirement that had preemptive effect under section 360k(a), even though that process applies to all class III devices and does not specify how any particular type of device is to be designed, manufactured, or labeled. In so holding, the court acknowledged that the PMA process permits a manufacturer to change "the design and labeling of the product ... without prior FDA approval to improve its safety and effectiveness" (16a-17a), but noted that the FDA can withdraw the product from the market if changes have rendered it unsafe or ineffective.[2]

Second, the court of appeals acknowledged the *Medtronic* majority's holding that state-law requirements of general

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[2] The court of appeals failed to note, however, that the FDA's ability to withdraw a product from the market is not unique to PMA devices. The FDA may recall or ban any class I, II, or III device in light of safety and effectiveness concerns. *See* 21 U.S.C. 360h(e), 360f. Moreover, devices cleared for marketing under the "substantial equivalence" standard—like the pacemaker component in *Medtronic*—may not be altered in a manner that affects safety and effectiveness without prior FDA approval. *See* 21 C.F.R. 807.81(a)(3).

applicability are not subject to preemption under section 360k(a), but rejected that holding on the ground that it is incompatible with Justice Breyer's view that at least some common-law claims would be preempted by the MDA (15a, 19a). The court of appeals came to this conclusion even though Justice Breyer formed part of the majority on this issue, and despite Justice Breyer's view that the agency's regulations on this topic were entitled to deference.

Having set forth these general principles, the court held that petitioners' strict liability and negligence claims are preempted. Without citation of authority, the court asserted that the FDA's marketing approval for Zyderm "constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling" (21a), and held that a strict liability verdict on any of these subjects under Indiana law would be different from, or in addition to, this federal "standard" (22a). A negligence verdict, the court held (22a), would also conflict with the PMA process for the same reason.[3]

The court of appeals then held petitioners' mislabeling and misbranding claims preempted because they "were **not** based on the requirements of the PMA, but were directed more generally to the labeling and branding practices of Collagen" (23a)(emphasis added). In this regard, the court did not address petitioners' argument that PMA products are subject to the same labeling rules that the *Medtronic* majority ruled were too general to have preemptive effect (*see* 116 S. Ct. at 2256-57), or the fact that the *Medtronic* majority relied on 21 C.F.R. 814.39(d), which permits manufacturers of PMA devices to change their labeling to enhance safety without FDA approval. *Medtronic*,

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[3] The court also held that petitioners' implied warranty claim is preempted on these grounds (25a).

116 S. Ct. at 2256 n.16.[4]

Finally, the Seventh Circuit held that petitioners' fraud claim—that respondent deliberately misled the FDA in obtaining approval for Zyderm—was also preempted. The court cited a pre-*Medtronic* decision from another circuit that came to the same conclusion (23a), but did not point to any federal "requirement" that addressed the issue of fraud or that would, under section 360k(a), conflict with a state-law remedy premised on respondent's misrepresentations.

REASONS FOR GRANTING THE WRIT

A. A Deep Post-*Medtronic* Split Exists Within the Federal and State Appellate Courts.

The decision below is illustrative of the deepening post-*Medtronic* split in authority in two important and interrelated respects. **First**, the decision below widens the division among the courts on whether *Medtronic* requires specificity on the state-law side of section 360k(a)'s preemption equation. As noted above, *Medtronic* held that, under section 360k(a), common-law claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices. The court of appeals acknowledged this majority holding and noted that it would, if applied to this case, require a ruling in favor of petitioners (15a). Nevertheless, the court of appeals did not follow this portion of the majority opinion on the ground that it is incompatible with Justice Breyer's concurrence (19a). Several other courts, including the Ninth Circuit, are in accord. *See Papike v. Tambrands, Inc.*, 107 F.3d

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[4] For the same reasons, the court of appeals held that petitioners' adulteration claim is preempted. It also rejected that claim on other grounds (23a & n.8).

737, 742 (9th Cir. 1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887 (Ct. App. 1997); *Fry v. Allergan Medical Optics*, 695 A.2d 511, 517 (R.I.), *cert. denied*, 1997 U.S. Lexis 6539 (1997) .

Although we strongly disagree with this reasoning (*see infra* at 17-18), for present purposes the significance of these rulings is that they are at odds with the rulings of other appellate courts that have held that this Court meant what it said in *Medtronic*: State laws of general applicability are not among those laws targeted for preemption by section 360k(a). In *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997), for instance, the plaintiff claimed that the defendant had failed to warn her about problems with a hip replacement device. Although the Tenth Circuit agreed with the defendant that there was at least one specific FDA-mandated warning that constituted a federal device "requirement" within the meaning of section 360k(a), it held that the plaintiff's failure-to-warn claim was not preempted because it was not based on a law relating specifically to medical devices:

> Like the failure to warn claim at issue in *Medtronic*, the general state common law requirements imposed by Oja's negligent failure to warn claim were not specifically developed "with respect to" medical devices. Instead, Oja's negligent failure to warn claim is predicated upon a general duty applicable to every manufacturer "to inform users and purchasers of potentially dangerous items of the risks involved in their use."

Id. at 789 (quoting *Medtronic*, 116 S. Ct. at 2258)(internal citations omitted). Other appellate courts have come to the same conclusion. *See Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997)(no preemption because "Kentucky's strict

liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under §360k"); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996)(same); *Kernats v. Smith Indus. Medical Sys.*, 669 N.E.2d 1300, 1309 (Ill. App. 1996)("plaintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt"), *cert. pending*, No. 96-1405; *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 686 (Mich. App. 1996)(same); *Baird v. American Medical Optics*, 693 A. 2d 904, 909-10 (N.J. Super., App. Div.)(same), *certification granted*, 700 A.2d 879 (N.J. 1997); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997)(same); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997)(same); *see also Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *17-*18 (N.D. Okla. Mar. 31, 1997)(same).[5]

Second, *Medtronic* held that, in order to have preemptive effect under 21 U.S.C. 360k(a), the federal "requirement" must be specific. Thus, as opposed to the comprehensive, but general, good manufacturing and labeling regulations held not to have preemptive effect in *Medtronic*, 116 S. Ct. at 2256-57, a specific labeling requirement for a particular type of device might have preemptive effect. *See, e.g.*, 21 C.F.R. 801.430. In his concurrence, Justice Breyer suggested that an example of

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[5] This split in authority is particularly acute in Illinois, where, if the complaint is filed in, or removed to, federal court, the plaintiff's claims are preempted under the decision below, but, if the complaint remains in state court, there is no preemption. *See Kernats*, 669 N.E.2d 1300. A similar problem arises in California, where, as the court of appeals noted (20a), the state's own appellate courts are split on this question. *Compare Armstrong*, 57 Cal. Rptr. 2d 763 (no preemption), *with Steele*, 63 Cal. Rptr. 2d 879 (preemption).

this type of specific federal requirement would be an FDA rule that a particular hearing-aid component be built with two-inch wires. *See* 116 S. Ct. at 2259.

Although the FDA's criteria for PMA applications are general and do not require devices to be designed, manufactured, or labeled in any particular manner, the court of appeals nonetheless held that the PMA process was a "specific" requirement principally because, in its view, the PMA process is more scientifically rigorous than the "substantial equivalence" clearance that the device at issue in *Medtronic* had received (16a). Other appellate courts have come to the same conclusion. *E.g.*, *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997); *Steele*, 63 Cal. Rptr. at 887-88. But as the court of appeals noted (15a & n.2), still other appellate and trial courts have come to the opposite conclusion, holding that PMA is **not** a specific requirement under *Medtronic*. *See Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen*, 1997 U.S. Dist. Lexis 6974, *14-*15.

In addition, two appellate courts have held that tort claims concerning class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. 360j(g))—which is similar, and often a precursor, to the PMA process—are not preempted because that process does not establish specific requirements under *Medtronic*. *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996)(en banc), *dismissed*, 117 S. Ct. 2429 (1997); *Niehoff*, 950 S.W.2d at 822. *Contra Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090 (6th Cir. 1997)(investigational device process does establish preemptive requirements), *cert. pending*, No. 96-1749.

In sum, this Court should grant the petition to resolve these conflicts among the federal and state appellate courts.

B. The Decision Below Is At Odds With *Medtronic*.

Review should also be granted because, in reaffirming its sweeping pre-*Medtronic* construction of section 360k(a), the court of appeals seriously misinterpreted *Medtronic*, leaving consumers injured by PMA devices without any damages remedy. The court of appeals erred in two fundamental ways.

First, the mere issuance of PMA is not a specific preemption-triggering requirement under section 360k(a). Although the criteria for issuance of a PMA are more rigorous than the marketing process at issue in *Medtronic*, 116 S. Ct. at 2247 (explaining differences), they are no more "specific." Both processes apply to class III devices generally (*id.*), and neither specifies how a product is to be designed, manufactured, or labeled. Thus, the PMA process contains no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. 801.420), or the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's concurrence. *Id.* at 2260. Indeed, as the Solicitor General has recently pointed out, the PMA process itself does not impose specific federal "requirements" because the device's specifications originate with the manufacturer, **not** with the FDA. Brief for the United States ("U.S. Br.") in *Smith Indus. Medical Sys., Inc. v. Kernats*, No. 96-1405, at 16; *cf. American Airlines, Inc. v. Wolens*, 115 S. Ct. 817, 824 (1995). And, as the court of appeals noted (16a-17a), a manufacturer does not need FDA approval to make changes to a PMA device that will enhance product safety. Thus, even if a state-law damages remedy were construed as "requiring" a manufacturer to improve product safety, that remedy would not be "different from, or in addition to" a federal

requirement.[6]

Second, the court of appeals' view that petitioners' claims are preempted, even though they are premised on state-law duties of general applicability, is based on an erroneous reading of *Medtronic*. The court of appeals recognized *Medtronic*'s majority holding that state laws of general applicability are not within section 360k(a)'s reach, but found Justice Breyer's joinder in that holding incompatible with his concurrence, in which he stated that a section 360k(a) "requirement" could encompass damages claims.

In the first place, the court of appeals was not free to ignore a majority holding of this Court, whatever its interpretation of a separate concurrence. Moreover, the two opinions are consistent with one another. Although state damages claims are ordinarily premised on duties of general applicability, such as the duty "to inform users and purchasers of potentially dangerous items of the risks involved in their use," *Medtronic*, 116 S. Ct. at 2258, or to use "reasonable care" in the design or manufacture of a product, a state's common law could, in some instances, require plaintiffs to prove their tort claims with the kind of specificity demanded by section 360k(a). *See* U.S. Br., at 17. For instance, under *Medtronic*, a jury instruction allowing the imposition of state-law liability on the ground that a medical device did not meet a particular state-created design,

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[6] The FDA has recently issued proposed regulations that reiterate "the agency's longstanding view that available legal remedies, including State common law tort claims, generally are not preempted" by the MDA. 62 Fed. Reg. 65384, 65384 (Dec. 12, 1997)(to be codified at 21 C.F.R. 808.1(d)(11)&(12)). Under the proposed regulations, the grant of PMA does not preempt state common-law actions. *Id.* at 65388 (proposed 21 C.F.R. 808.1(d)(12)). The agency's views underscore the need for this Court to review the lower courts' contrary interpretations of section 360k(a).

manufacturing, or warning specification might meet section 360k(a)'s specificity requirement. *See Connelly*, 927 S.W.2d at 854. Similarly, a negligence per se claim premised on violation of a specific state statutory requirement applicable to medical devices might be preempted if it imposed a duty different from that imposed by an FDA requirement on the same subject. Indeed, this is precisely the analysis of section 360k(a) contained in Justice Breyer's concurrence, where he said that a **specific** federal regulation demanding a two-inch hearing-aid wire would preempt a common-law claim premised on a **specific** state-law requirement for a one-inch wire. *Medtronic*, 116 S. Ct. at 2259 (Breyer, J., concurring).

Aside from these basic errors, the court of appeals also misapplied *Medtronic* in resolving petitioners' mislabeling, misbranding, and fraud claims. As to mislabeling and misbranding, the court of appeals appears to have correctly construed those claims as encompassing state-law enforcement of MDA labeling and misbranding requirements (22a), but nonetheless held that they are preempted by Zyderm's PMA (23a). The issuance of a PMA, however, does not preempt state-law enforcement of **other** MDA requirements. *Medtronic* held, without qualification, that a state tort claim premised on a violation of an MDA requirement is not preempted because it is not, under section 360k(a), "different from, or in addition to" the federal requirement. 116 S. Ct. at 2255-56 (majority); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). Class III devices that have been granted PMA, just like the substantially equivalent device in *Medtronic*, are subject to the FDA's labeling requirements (*see* 21 C.F.R. 801.109). Thus, petitioners are free to pursue a mislabeling claim under Indiana law if it is consistent with those federal requirements.

As to petitioners' claim that respondent fraudulently obtained approval for Zyderm, the court of appeals relied for its preemption holding on *Michael v. Shiley, Inc.*, 46 F.3d 1316,

1328-39 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995), which held that, if fraud is perpetrated on the agency, it is up to the FDA, not the tort system, to redress the problem. This analysis is faulty for at least two reasons. First, preemption under section 360k(a) is triggered only where specific federal and state requirements on the same subject are in conflict. *See Medtronic*, 116 S. Ct. at 2261 (Breyer, J., concurring). The PMA process, which considers a device's safety and effectiveness (*see* 21 U.S.C. 360e(d)), does not establish "requirements" that have anything to do with respondent's alleged fraud, and the court of appeals did not suggest otherwise. Therefore, a jury award premised on a fraud-on-the-FDA theory would not, under section 360k(a), establish a state-law "requirement" relating to Zyderm that is "different from, or in addition to" any overlapping MDA requirement. *Accord Connelly*, 927 S.W.2d at 851.

Second, the court of appeals erred in holding that petitioners' fraud-on-the-FDA claim is preempted simply because the FDA has authority to police deception in the PMA process. Even if it could be said that MDA requirements demanding truthfulness in dealings with the FDA (*e.g.*, 21 U.S.C. 352(a); 21 C.F.R. 814.37(d),(e)), were the federal-law counterparts to petitioners' state-law fraud claim, nothing in section 360k(a) gives the FDA exclusive authority to enforce those requirements. *See Medtronic*, 116 S.Ct. at 2261 (Breyer, J., concurring)(MDA does not occupy field of device regulation); U.S. Br., at 13 (MDA "does not establish a rule of primary jurisdiction to adjudicate individual disputes"). To the contrary, in *Medtronic*, the Court acknowledged that the FDA brings actions to curb violations of its good manufacturing practices rules (116 S. Ct. at 2256), but held that state-law damages actions premised on those (or any other) MDA violations are not preempted. "[T]he presence of a damages remedy does not amount to the additional or different

'requirement' that is required [for preemption] under the statute; it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Medtronic*, 116 S. Ct. at 2255 (majority); *accord id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). Thus, as with all of petitioners' claims, allowing a state-law fraud claim to go forward fosters, rather than undermines, the federal interest in device regulation.

In sum, review should be granted because the court of appeals' sweeping preemption holding is irreconcilable with this Court's decision in *Medtronic*. There has been ample percolation in the lower courts; it is time for this Court to end the divergence and confusion.

CONCLUSION

For the reasons stated above, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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December 19, 1997

APPENDIX

In the
United States Court of Appeals
For the Seventh Circuit

No. 94-3946

BARBARA MITCHELL and GREGORY MITCHELL,

Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Indiana, Hammond Division.
No. 93 C 283--James T. Moody, Judge.

ARGUED DECEMBER 13, 1996--DECIDED
SEPTEMBER 23, 1997

Before CUDAHY, RIPPLE and KANNE, Circuit Judges.

RIPPLE, Circuit Judge. This case is before the court on remand from the Supreme Court of the United States. The Court has directed us to reconsider our earlier decision in light of the Court's intervening decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). See *Mitchell v. Collagen Corp.*, 116 S. Ct. 2576 (1996) (granting certiorari, vacating our judgment and remanding for consideration in light of *Medtronic*).

In their complaint, the Mitchells alleged various state law

claims arising out of collagen-based injection treatments that Mrs. Mitchell received. Collagen Corporation ("Collagen") sought summary judgment, on the ground that all the Mitchells' claims were preempted by the Medical Devices Amendments ("MDA"), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.* The district court granted summary judgment to Collagen on the ground that the state law claims were preempted. *See Mitchell v. Collagen*, 870 F. Supp. 885 (N.D. Ind. 1994). We affirmed the grant of summary judgment, relying, with respect to some of the claims, on Collagen's defense of preemption and, with respect to other claims, on the Mitchells' failure to meet their burden of coming forward on summary judgment with an adequate factual showing to warrant trial. *See Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995) ("*Mitchell I*"). After reconsidering this case in light of the Supreme Court's *Medtronic analysis*, we affirm the judgment of the district court.

I
BACKGROUND

A. Facts

We shall assume familiarity with the facts set out in *Mitchell I*. We limit our rendition here to those matters relevant to the task at hand.

In 1988, Barbara Mitchell received several injections of Zyderm or Zyplast (collectively "Zyderm"), collagen-based products produced by Collagen. Zyderm is used to fill in soft tissue under skin or scars when tissue has been lost due to injury, trauma, age, infection or other diseases. The collagen-based product is injected into the layers of the skin where there is a depressed scar or indentation. Zyderm acts as a replacement for the soft tissue that has been lost in this area

and is classified as a Class III medical device.

Class III medical devices are those that operate "to sustain human life, are of substantial importance in preventing impairment of human health, or pose a potential unreasonable risk of illness or injury." *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1245 (7th Cir. 1997). Before a Class III device may be introduced to the market, the manufacturer must provide the Food and Drug Administration ("FDA") with a reasonable assurance that the device is safe and effective under the MDA. *Medtronic*, 116 S. Ct. at 2246. To provide that assurance, a manufacturer must obtain premarket approval ("PMA") from the FDA. This procedure is a "rigorous" process, in which the manufacturer much submit detailed information to the FDA regarding the safety and effectiveness of the device. *Id.* at 2247. Manufacturers must provide the FDA with samples of the device, an outline of the device's components and properties, a description of the manufacturing process, copies of the proposed labels, various other data and information, and any other information the FDA requests. 21 C.F.R. § 814.20. The FDA spends an average of 1,200 hours per PMA application reviewing these materials.

The FDA initially approved Collagen's PMA for Zyderm in 1981. During 1991-92, the FDA conducted a reexamination of Zyderm and concluded that its decision to approve Zyderm's PMA was appropriate.

There are several exceptions to the PMA requirement. These exceptions have demonstrated a propensity for swallowing the rule. *See Medtronic*, 116 S. Ct. at 2247-48 (cataloging the lopsidedness of Class III devices introduced under the "substantially equivalent" procedures rather than under the PMA process). First, products that were introduced into or distributed to be introduced into interstate commerce prior to May 28, 1976 are grandfathered from this requirement until the FDA initiates and completes the PMA process for such devices. 21

C.F.R. § 814.1(c)(1). Second, those devices that are "substantially equivalent" to grandfathered products are exempt from the PMA process until the FDA initiates and completes the PMA process for such products. *Id.* In stark contrast to the PMA process, the FDA determination of whether a Class III device is substantially equivalent to another device already on the market is completed, on average, in only 20 hours. *Medtronic*, 116 S. Ct. at 2247.

B. Earlier Proceedings

1.

The Mitchells filed a multi-count complaint against Collagen in Indiana state court. Their complaint alleged counts of strict liability, negligence, fraud, mislabeling, misbranding, adulteration and breach of warranty. Collagen removed the case to federal court and moved for summary judgment. The district court granted Collagen's motion. It reasoned that the Mitchells' state law claims were preempted by the MDA. The court determined the scope of federal preemption by focusing on the MDA's preemption provision and the FDA's regulations. The MDA proscribes states from establishing "any requirement . . . which is different from, or in addition to, any [federal] requirement" established under the MDA. 21 U.S.C. § 360k(a).[1]

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[1] Section 360k(a) provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device

The regulations clarify that a state requirement can include requirements established by court decision. *See* 21 C.F.R. sec. 808.1(b). The district court concluded that Congress intended the MDA preemption provision to be read to preempt common law causes of action. It reasoned that the PMA process for Class III medical devices constitutes a requirement under the MDA and that, consequently, any state requirement that implicated the requirements imposed by the PMA process was a requirement "different from, or in addition to," the federal requirements. The district court therefore granted Collagen's motion and dismissed all the state law counts as preempted by federal law, except for Mr. Mitchell's derivative claim for loss of consortium. This claim was dismissed because the remaining claims were preempted.

2.

We affirmed the judgment of the district court, although we did not rely exclusively on preemption grounds. We began by noting that the question of whether a state cause of action is preempted by federal law "'is a question of congressional intent.'" *Mitchell I*, 67 F.3d at 1274 (quoting *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994)). Relying primarily on the plain wording and language of the MDA preemption clause,

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under this chapter.

21 U.S.C. § 360k(a). The pertinent FDA regulation provides:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. 21 C.F.R. § 808.1(d).

we concluded that "[t]he phrase 'any requirement' in 21 U.S.C. § 360k(a) is broad enough to include at least some common law causes of action within the statute's preemptive scope." *Id.* at 1276; *cf. Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) (holding that state requirement under Public Health Cigarette Smoking Act of 1969 preemption provision encompasses common law causes of action). In considering the FDA's preemption regulations under the MDA and the structure of the Amendments, we also concluded that the PMA process constitutes a specific federal requirement for preemption purposes under 21 U.S.C. § 360k(a).

We then turned to the individual claims and analyzed them in light of these conclusions to determine whether they would add requirements "different from, or in addition to," the PMA process. First, we dealt with the Mitchells' strict liability claim and their negligence claims. The strict liability claim alleged that Collagen "knew or in the course of reasonable care should have known" that Zyderm was "unreasonably dangerous and had the potential for causing serious immunological and/or autoimmune reactions, damage and injuries when injected into humans for its intended use and purpose." Compl. at 2-3. The negligence claims alleged that the product was accompanied by inadequate warnings and that Collagen had been negligent in the design, testing, approval, manufacturing, marketing and sale of Zyderm. We held that these claims were preempted by the MDA. We further concluded that, to the extent that the mislabeling, misbranding and adulteration claims alleged violations of state law despite Collagen's conformity to the FDA's requirements, these claims also were preempted. However, to the extent that the Mitchells' claims for mislabeling, misbranding and adulteration alleged that Collagen had not followed the FDA requirements, the claims were not preempted because, in permitting a cause of action for non-conformity with federal requirements, state law did not impose a requirement

"different from, or in addition to," the federal requirements.

Upon examination of the Mitchells' mislabeling, misbranding and adulteration claims, however, we determined that only the Mitchells' adulteration claim could be construed as falling into this non-preempted category, and that claim, we concluded, could not survive the motion for summary judgment because the Mitchells had failed to present sufficient evidence. We agreed with the district court that the Mitchells' claims of Collagen's fraud on the FDA and of implied warranty were also preempted. Finally, we determined that, although one possible fraud claim and the express warranty claims would not be preempted by the MDA, Collagen was still entitled to summary judgment on these claims because the Mitchells had not come forward with sufficient evidence to defeat the summary judgment motion.

We therefore affirmed the judgment of the district court dismissing all of the Mitchells' claims. The Mitchells then filed a petition for certiorari in the Supreme Court. The Court granted that petition, vacated our earlier decision, and invited us to reconsider the Mitchells' claims in light of its decision in *Medtronic v. Lohr*, 116 S. Ct. 2240 (1996).

II
DISCUSSION
A.

We begin our analysis by turning to the decision of the Supreme Court in *Medtronic*. At the outset, we think it is important to stress that the factual situation before the Court in *Medtronic* was substantially different from the one before us today. In *Medtronic*, the Supreme Court dealt with the scope of the preemption provision of the MDA in the context of the expedited "substantially equivalent" process, not the full PMA process to which the Collagen product was subjected.

Medtronic involved a malfunctioning pacemaker. Lora Lohr and her husband filed their action against *Medtronic* after Ms.

Lohr's pacemaker, a Class III medical device, malfunctioned. As we have just noted, the pacemaker had not gone through the PMA process, but was allowed to be marketed because the FDA determined that it was substantially equivalent to a device already on the market. The Lohrs' complaint alleged a number of counts of negligence and strict liability. The Court of Appeals for the Eleventh Circuit determined that the MDA preempted at least some common law actions. It held that the non-design claims were preempted because the FDA's good manufacturing and labeling regulations establish preemptive federal requirements. The court also held that the negligent and strict liability design claims were not preempted because the "substantially equivalent" determination was not a decision with respect to the pacemaker's safety.

The Supreme Court reversed with respect to the preempted claims. The majority began by noting that the MDA contains a provision that expressly preempts state law. *Medtronic*, 116 S. Ct. at 2250. Therefore, continued the Court, the task was not to determine whether state law is preempted by the MDA but rather to determine the degree to which state law is preempted. Its task defined, the Court began its analysis by recalling two basic principles that traditionally govern preemption analysis. It first recalled that, "because the States are independent sovereigns in our federal system, . . . Congress does not cavalierly pre-empt state-law causes of action." *Id.* Next, it noted that the purpose of Congress is the "ultimate touchstone in every preemption case." *Id.* (quotation and citation omitted).

At this point, there was disagreement among the Justices with respect to the appropriate analysis. Justice Stevens, writing for himself and three other Justices, rejected Medtronic's assertion that the preemption provision of the statute, 21 U.S.C. § 360k(a), *see* note 1, *supra*, preempted any common law cause of action because such a cause of action is a "requirement." These Justices found such an assertion to be "implausible." 116

S. Ct. at 2251. In their view, because the federal act does not provide for a private cause of action, Medtronic's construction of the preemption statute would "have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order 'to provide for the safety and effectiveness of medical devices intended for human use.'" *Id.* (quoting Pub. L. No. 94-295, 90 Stat. 539 (preamble to the Act)). These Justices continued that it was difficult to believe that Congress would have removed all avenues of legal redress without significant discussion. The use of the term "requirement," the Justices continued, suggests a focus on "device-specific enactments of positive law by legislative or administrative bodies, not the application of general rules of common law by judges and juries." *Id.* at 2252. Moreover, remarked these Justices, there is no indication in the history of the Act that the drafters feared that the operation of the state common law system would frustrate the purposes of the Act to protect the consumer of medical goods without unduly frustrating innovation.

A contrary view with respect to the preemptive effect of the MDA on state common law causes of action was expressed by Justice O'Connor in an opinion joined by three other Justices. In the view of these members of the Court, a common law duty was a "requirement" within the meaning of the MDA because common law causes of action "operate to require manufacturers to comply with common-law duties." *Id.* at 2262 (O'Connor, J., concurring in part and dissenting in part). Therefore, concluded the Justices, a fair reading of the statute "indicates that state common-law claims are preempted . . . to the extent that their recognition would impose 'any requirement' different from, or in addition to, FDCA requirements applicable to the device." *Id.* at 2263 (O'Connor, J., concurring in part and dissenting in part). Unlike the Justices joining Justice Stevens' opinion, these

members of the Court did not believe that the state common law had to be "specific" to be preempted. It simply had to be "different from, or in addition to," any requirement of federal law. Turning to the case before them, these same Justices therefore concluded that the Lohrs' defective design claim was not preempted by the substantial equivalency process. This process, pointed out Justice O'Connor, merely determines whether the device in question is the substantial equivalent of another device already on the market. It places no "requirement" on the device. Nor did these Justices believe that any cause of action based on a failure to comply with federal requirements was preempted because enforcement of a federal requirement is not a requirement that is "different from, or in addition to," the requirements imposed by federal law. Moreover, the Justices continued, the availability of a damages remedy does not interfere with the federal scheme. The statute forbids imposing an additional requirement, not an additional remedy. However, these Justices continued, some of the Lohrs' manufacturing and labeling claims would compel Medtronic to comply with requirements "different from, or in addition to," those required by the FDA and thus would be preempted. Similarly, the Lohrs' failure to warn claim was preempted because the FDA has set forth extensive and exclusive requirements in this area.

With eight of the Justices evenly divided into the two camps described above, the separate views of Justice Breyer supplied the determining vote in establishing the Court's holding. On the crucial issue of whether the MDA could ever preempt a state common law cause of action, the Justice found himself in basic agreement with Justice O'Connor: "One can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 2259 (Breyer, J., concurring). To illustrate his conclusion, the Justice posited a situation in which an MDA regulation required that a hearing aid contain a 1-inch wire, but

a state regulation required a 2-inch wire. That MDA regulation would preempt the state regulation. The same result ought to obtain, reasoned Justice Breyer, if a state tort action were to impose liability on the failure to have a 2-inch wire. Consequently, wrote the Justice, "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 2260 (Breyer, J., concurring). In determining whether the state tort actions before him were preempted, the Justice noted that, given the broad, highly ambiguous language of the statute, "Congress must have intended that courts look elsewhere for help as to just which federal requirements pre-empt just which state requirements, as well as just how they might do so." *Id.* (Breyer, J., concurring). The "elsewhere" to which the Justice referred was "the relevant administrative agency" with its "rules, regulations, or other administrative actions." *Id.* (Breyer, J., concurring). Focusing on the FDA's regulations, the Justice then noted that the FDA, by regulation, had provided that state requirements were preempted only when "'specific [federal] requirements applicable to a particular device' made 'any existing divergent State . . . requirements applicable to the device different from, or in addition to, the specific [federal] requirements.'" *Id.* at 2260-61 (Breyer, J., concurring) (quoting 21 C.F.R. § 808.1(d) (1995)) (brackets, ellipsis and emphasis in original).

The Court then turned to a disposition of the particular claims before it. Despite the differences outlined above, the unanimous Court rejected Medtronic's argument that the "substantially equivalent" determination by the FDA preempted the state claims based on defective design:

> There is no suggestion in either the statutory scheme or the

> legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo[, which] . . . included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design.

Medtronic, 116 S. Ct. at 2254-55. Keeping in mind that congressional purpose is the touchstone of preemption analysis, the Court concluded that, given the background of the § 510(k) process and the presumption against preemption, the design claims were not preempted.

The unanimous Court also held that, to the extent a common law action mirrors the FDA regulations, it would not be preempted. Nothing in the MDA, held the Court, denies the state "the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 2255. Additional state requirements that would make the federal requirement narrower, not broader, might be different from the federal regulations in the literal sense but provide no reason to infer that Congress intended preemption. The addition of a damages remedy likewise does not create a preemption situation. It merely provides an additional reason for the manufacturer to comply with the federal regulations.

The views of the Justices joining in Justice Stevens' opinion and the views of Justice Breyer permitted the Court to form a majority for the disposition of the manufacturing and labeling claims. The FDA regulations provide that state requirements are preempted only when the FDA has established "'specific counterpart regulations or . . . other specific requirements applicable to a particular device.' 21 CFR § 808.1(d) (1995)." 116 S. Ct. at 2257 (ellipsis in original). Furthermore, preemption is not intended when the state requirements are "of general applicability where the purpose of the requirement

relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1). Although the Court specifically did not conclude that "general" federal requirements could never preempt state requirements or that "general" state requirements could never be preempted by federal requirements, the Court discerned an

> overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest. . . . The statute and regulations, therefore, require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations.

116 S. Ct. at 2257-58 (footnote omitted). When performing this comparison, courts are to be mindful that state requirements of general applicability are not preempted unless they establish a substantive requirement for a specific device and that the federal requirements, to be preemptive, must be specific to a particular device. *Id.*

Applying these principles, a majority of the Court found none of the Lohrs' claims to be preempted because of their generality and because of the generic nature of the federal requirements at issue there. In summarizing, the Court wrote:

> The generality of [the requirements at issue] make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal

> requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements.
>
> Similarly, the general state common-law requirements in this case were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations. . . . These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers.

Medtronic, 116 S. Ct. at 2258.

This case presents a difficult situation for an intermediate appellate court. The basic issue of statutory construction presented by the case is, as the Supreme Court noted in *Medtronic*, a difficult one. The implementing regulation of the FDA is likewise imprecise and fails to address squarely the issue of preemption by common law causes of action. Lastly, although we have an obligation to be absolutely faithful to the holdings of

the Supreme Court of the United States, the holding in *Medtronic* contains several ambiguities that impair our ability to perceive with absolute clarity the path that the Court has chosen for us to follow.

The ambiguity central to our task is the tension between the holding of the Court embodied in the text immediately above and Justice Breyer's belief, essential to the formation of a majority, that at least some state-based causes of action would be preempted by the MDA. Like the majority of courts that already have had to deal with this quandary, we believe that the *Medtronic* disposition must be read as acknowledging that at least some state-based common law causes of action must be considered "requirements" as that term is employed in the MDA. Before we address, with more specificity, this ambiguity, which is central to our decision, we must pause to address a threshold matter that is also very important to our analysis and that, both analytically and as a matter of prudent presentation, must be confronted first.

B.

As we have noted once already, the PMA process to which Zyderm was subjected in this case is substantially different from the "substantially equivalent" process at issue in *Medtronic*. Although there is some authority to the contrary,[2] we believe that the PMA process constitutes a specific federal regulation of

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[2] *See Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997) (holding that the PMA process is not a specific regulation because the requirements are not contained in a formal regulation); see also *Lakie v. SmithKline Beecham*, 965 F. Supp. 49, 1997 WL 286209 at *3-*4 (D.D.C. Mar. 5, 1997) (holding, without extensive discussion, that the PMA process is not a specific federal requirement).

the product.[3] The Supreme Court of Rhode Island, in *Fry v. Allergan Medical Optics*, 695 A.2d 511, 1997 WL 351255 (R.I. June 19, 1997), faced this question in a case involving an intraocular lens and dealt with it with exceptional clarity. In determining that the PMA process was a specific federal regulation, as that term is employed in *Medtronic*, the court noted that the PMA process "involved a review of all the ingredients, components, manufacturing methods, and labeling to be used in conjunction with the lens." *Id.* at *5. The court concluded:

> We think rather than expressing entirely generic concerns of safety, the FDA has expressed explicit concerns toward this lens. We conclude that the premarket approval process constitutes a specific federal interest as contemplated in *Medtronic* and that, therefore, the FDA approval served to impose strict FDA requirements upon the defendant.

Id.

Dealing with the same product as the one now before us, the California Court of Appeal, in *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887 (Ct. App. 1997), held that the PMA procedure did amount to a specific regulation of Zyderm. The court contrasted the PMA process and the "substantially equivalent" process at issue in *Medtronic*. It emphasized that the PMA process imposed requirements that directly affected the safety and effectiveness of the product. Indeed, although the design and labeling of the product might be changed without

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[3] For an excellent description of the PMA process, see *Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095-96 (6th Cir. 1997), *pet'n for cert. filed*, 65 U.S.L.W. 3755 (U.S. May 1, 1997) (No. 96-1749).

prior FDA approval to improve its safety or effectiveness, the product is subject to withdrawal from the market if the FDA determines that the changes have rendered the product unsafe or inadequate.

We agree that the PMA process, as opposed to the "substantially equivalent" process at issue in *Medtronic*, can constitute the sort of specific federal regulation of a product that can have preemptive effect. During the PMA process, the federal government, it can truly be said, has "'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.'" *Papike v. Tamrands, Inc.*, 107 F.3d 737, 741 (9th Cir. 1997) (quoting *Medtronic*, 116 S. Ct. at 2258), pet'n for cert. filed, 66 U.S.L.W. 3107 (U.S. July 15, 1997) (No. 97-94).

C.

We are now to the point at which we can return to the ambiguity created by the tension between Part V of the majority's opinion in Medtronic and the separate but essential views expressed by Justice Breyer. Here the path already has been cleared, at least partially, by our colleagues on another panel of this court. In Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997), Judge Rovner, then dealing with a medical device approved under the "investigational device exception" (IDE) for Class III devices, examined the effect of a state court judgment to determine whether the maintenance of a particular common law cause of action would result in the frustration of the FDA's requirements. Writing for the court, she held that state common law claims for strict liability and implied warranty of merchantability would impose greater burdens on the

manufacturer than those imposed by the FDA and therefore were preempted. On the other hand, a negligent manufacturing claim that simply alleged that the manufacturer had not complied with the requirements of the FDA did not impose state requirements that were different from or in addition to those imposed by the FDA and therefore was not preempted. This court's approach in *Chambers*, although dealing with a different aspect of the MDA from the one before us, is a significant analytical pathfinder because it recognizes that, in order to determine whether a common law cause of action is preempted by the action of the FDA, it is necessary to examine the state law cause of action at a sufficiently precise level of generality to determine whether the final judgment of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.

In adopting this analysis, Judge Rovner distinguished the decision of our colleagues in the Sixth Circuit in *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090 (6th Cir. 1997), on the ground that the Ohio statutory claims involved in that litigation would have imposed on the manufacturer requirements greater than those imposed by the FDA. Notably, however, although our courts differ with respect to the result required in the particular case, they do not differ with respect to essential analysis. Judge Kennedy, writing for the Sixth Circuit, employed the same approach that Judge Rovner applied in our circuit. She examined the state statute, which admittedly applied on its face to products other than the medical device in question, and held that it was preempted because "it is the kind of requirement that would impede the implementation and enforcement of specific federal requirements." *Martin*, 105 F.3d at 1099.

The approach that this circuit and the Sixth Circuit have taken in determining whether state common law causes of action are preempted by the MDA is also the approach of the Ninth

Circuit. In *Papike*, the court addressed specifically the difficulty caused by a comparison of the language in Justice Breyer's separate opinion and Part V of the majority opinion which the Justice also joined. The court concluded that

> it makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the MDA, and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements.

Papike, 107 F.3d at 742.[4] Other courts, faced with the same dilemma, have reached the same common-sense conclusion. *See, e.g., Chmielewski v. Stryker Sales Corp.*, 966 F. Supp. 839, 1997 WL 348935, at *3 (D. Minn. June 17, 1997). In *Fry v. Allergan Medical Optics*, 695 A.2d 511, 1997 WL 351255 (R.I. June 19, 1997), for example, the Supreme Court of Rhode Island held that state claims based on theories of negligence, strict liability and breach of warranty, "insofar as these claims

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[4] Our colleagues in the Tenth Circuit appear to have deviated from this general approach and require that the state "requirement" be developed specifically "with respect to" the medical device. It appears that the Tenth Circuit would hold therefore that generic common law causes of action do not meet this test because, when stated without application to a particular product, they cannot be said to have been developed "in relation to" the medical device in question. *See Oja v. Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) (holding that, in a case involving a Class II medical device, state common law claims for negligent failure to warn and negligence in manufacture were not state requirements developed "with respect to" medical devices and therefore not preempted under Medtronic).

threaten to impose different or additional burdens on the defendant," *id.* at *6, are preempted. Had the plaintiff's state law claims alleged a departure from the FDA-imposed standards, said the court, those claims would not be preempted because "they would not impose different or additional requirements but would instead merely enforce the exact requirements imposed by federal law." *Id.* In a case that involved the same product as the one in this case, the California Court of Appeal, disagreeing with an earlier case from another district, *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763 (Ct. App. 1996),[5] decided that "state requirements in the form of standards of care or behavior are preempted and cannot form the basis of a state common law claim for damages if they are different from or in addition to the specific federal requirements arising from the PMA process." *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 888 (Ct. App. 1997). The Florida District Court of Appeal, ruling in *Hernandez v. Coopervision, Inc.*, 691 So. 2d 639 (Fla. Dist. Ct. App. 1997), also employed a methodology that is faithful to the mandate of *Medtronic*. The party claiming preemption, ruled the court, must demonstrate that "there is a conflict between the state and federal regulations of the medical devices which threatens to interfere with a specific federal interest." *Id.* at 641.

The Pennsylvania Supreme Court, in *Green v. Dolsky*, 685 A.2d 110 (Pa. 1996), *cert. denied*, 117 S. Ct. 1432 (1997), also recognized the fundamental difference between "substantially equivalent" cases such as *Medtronic* and PMA cases. It

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[5] *See also Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300 (Ill. App. Ct. 1996) (holding that both statutory and common law causes of action were not preempted because they had not been specifically developed with respect to medical devices), *pet'n for cert. filed*, 65 U.S.L.W. 3632 (U.S. Mar. 4, 1997) (No. 96-1405).

acknowledged that state common law causes of action could frustrate the congressional intent with respect to the MDA just as readily as other state regulatory devices. Although we have no need in this case to comment on all the Pennsylvania court's determinations of what is preempted and what is not preempted, it is noteworthy that it articulated several basic corollaries that are helpful. The court determined that (1) state claims that allege that FDA requirements have not been observed are not preempted, and (2) state claims that conflict with specific requirements of the FDA are preempted. The court specifically noted that state common law claims are preempted if they attempt to substitute a reasonableness analysis, characteristic of negligence claims, for the judgment of the FDA in approving the development and distribution of this particular product in the course of the premarket approval process. *Green,* 685 A.2d at 117.

D.

We now turn to the case before us and reevaluate each of the Mitchells' claims in light of our analysis of the Supreme Court's decision in *Medtronic.*

As we pointed out in *Mitchell I,* 67 F.3d at 1280, the Mitchells' strict liability claim consists of allegations that Zyderm was an unreasonably dangerous product and that Collagen knew or should have known that Zyderm was unreasonably dangerous and had the potential for causing serious immunological and/or autoimmune reactions, damage and injuries when injected into humans. We believe that this claim is preempted by the PMA process for a Class III medical device. Approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling. The FDA's determination is specific to the product. A state court judgment premised on a contrary determination, as a finding of liability based on the Mitchells' strict liability claim

necessarily would be, would constitute, for the reasons we have stated earlier, a requirement "different from, or in addition to," the standard required by federal authority.

The Mitchells' negligence claims must be considered preempted to the extent that they allege that Collagen was negligent despite its adherence to the standards required by the FDA in its PMA for this specific product. A state court judgment premised on a determination that such a specific allegation is true would necessarily conflict with the determination of the FDA that its requirements rendered the product safe and effective.[6]

We come next to the Mitchells' mislabeling, misbranding and adulteration claims. Again, to the extent that these allegations claim that Collagen has incurred liability under state law despite its conformity to the requirements of the PMA, the state law claims must be considered preempted. Permitting such claims would add requirements that are "different from, or in addition to," those established through the PMA process. However, to the degree that these claims may be read to allege that Collagen failed to meet the standards set forth in the PMA process, the allegations are not preempted; a state judgment premised on the truth of those allegations would not set up a requirement "different from, or in addition to," those established by the FDA. Such a state judgment simply would enforce the standard embodied in the federal PMA. Absent an explicit determination by the FDA that such a judgment would interfere with the operation of the federal scheme, we do not believe that

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[6] To the extent that the Mitchells' complaint may be read as alleging that Collagen was negligent in its adherence to the standards of the FDA in the PMA, the negligence claim would not be preempted. It would, however, be subject to dismissal on the merits because the Mitchells failed to meet their burden on summary judgment.

Medtronic affords a basis for our assuming such interference.[7] In our earlier opinion, however, we determined that the Mitchells' mislabeling and misbranding claims were not based on the requirements of the PMA, but were directed more generally to the labeling and branding practices of Collagen. As did the district court, we further assumed that the adulteration claim was precluded by the Mitchells' failure to come forward on summary judgment with sufficient evidence to counter Collagen's assertion that the product had been free from adulteration throughout its manufacturing history under the PMA.[8]

The Mitchells' complaint also alleges that Collagen committed fraud through its representations to the FDA during the PMA process. We do not believe that our earlier decision that this claim is preempted is altered by *Medtronic*. We continue to believe that this issue was decided correctly by the Third Circuit in *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1328-29 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995).

As we pointed out in our earlier opinion, the Mitchells also

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[7] *See* 21 C.F.R. § 808.1(d)(2) (stating that state or local requirements "equal to, or substantially identical to," federal requirements imposed under the PMA are not preempted).

[8] The Mitchells contend that we ought to revisit this question. It was addressed by the district court in its opinion, *see Mitchell v. Collagen*, 870 F. Supp. 885, 896-97 & n.19 (N.D. Ind. 1994), by this panel in our original opinion and on petition for rehearing. We do not believe that the Supreme Court's opinion gives us any reason to revisit the matter again. It is sufficient to say that we have traced carefully the long and convoluted motions practice in the district court, and we are satisfied that the district court did not commit reversible error in its determination that both parties had been given an adequate opportunity to address the merits.

alleged that Collagen had committed fraud through misrepresentations about the product. To the extent that this allegation is based on the labeling of the product in conformity with the PMA requirements of the FDA, the claim is preempted for the same reasons that similar misbranding and mislabeling claims are preempted. The sufficiency of this information has been approved explicitly by the FDA.

In our earlier opinion, we noted that, on appeal in their reply brief to this court, the Mitchells contended that the fraud allegation also encompassed allegations of fraud in advertising and promotional materials. In our earlier opinion, we held in the alternative that, even if the Mitchells were given the benefit of the doubt with respect to the specificity of these claims--and we continue to believe that the claims are too vague--their claims could not survive. First of all, as we pointed out in our earlier opinion, Collagen submitted, through an exhibit attached to the affidavit of Dr. Erickson, a statement noting that the FDA had regulated advertising with respect to Zyderm. The Mitchells have not disputed this submission. Therefore, it must be accepted as admitted that promotional materials were subject to regulation under this PMA. As a consequence, these claims would survive only to the degree that they allege that the material did not conform to the specifications of the PMA. However, even if we make that assumption, the Mitchells have failed to meet their burden on summary judgment. The district court's grant of summary judgment must stand.

The Mitchells also alleged in their complaint the following warranty claim: "At all material times, Defendant, Collagen Corporation . . . warranted and represented to Plaintiff, Barbara Mitchell, that [Zyderm] was safe for [its] intended use and purpose." Compl. at 2. As we noted in our earlier opinion, the Mitchells did not specify the nature of the alleged warranty or its substance before the district court.

If the Mitchells meant to allege an implied warranty, it is

preempted. As we noted in our earlier opinion, an implied warranty claim is based on the accepted standards of design and manufacture of the products. In the case of a product that has gone through the PMA process, these criteria are set by the FDA. A state judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it. Accordingly, such a claim is preempted.

An express warranty claim poses a different situation. As we noted in our earlier opinion, such warranties arise from the representations of the parties and are made as the basis of the bargain between them. A state judgment based on the breach of an express representation by one of the parties does not necessarily interfere with the operation of the PMA, and therefore we cannot say that such a cause of action is preempted. Nevertheless, as we noted in our earlier opinion, we do not believe that the Mitchells can assert such a claim at this stage of the litigation. They have never specified whether their claim was based on an express or an implied warranty. Nor have they ever stated the nature of any express warranty. The district court was therefore entirely justified in granting summary judgment.[9]

Conclusion

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[9] We note that we would reach this result even if we were to accept the Mitchells' characterization of the summary judgment as one limited only to the issue of preemption. Assuming arguendo the correctness of that view, it still would have been incumbent on the district court to grant the motion. Without any indication from the Mitchells that the warranty was express rather than implied and without indication as to the substance of any express warranty, they could not have prevailed.

For the foregoing reasons, the judgment of the district court is affirmed.

AFFIRMED

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA,
HAMMOND DIVISION

BARBARA and GREGORY MITCHELL,
Plaintiffs,
v.

COLLAGEN CORPORATION,
Defendant.

No. 2:93 cv 283 JM

November 7, 1994

ORDER and MEMORANDUM OPINION

This is a diversity action in which plaintiffs, the Mitchells, allege that Barbara Mitchell was injured by injections of collagen compounds, Zyderm and Zyplast, manufactured by defendant Collagen Corporation ("Collagen"). The Mitchells seek recovery under several alternative Indiana tort law theories. Before the court for decision is a motion for summary judgment filed by Collagen, and two motions filed by the Mitchells seeking to amend their complaint.

Motions to Amend Complaint

In both motions the Mitchells seek to add to their complaint a claim that Collagen has violated provisions of the Indiana Deceptive Consumer Sales Act, Ind. Code §§ 24-5-0.5-1 et seq. A brief summary of the posture of the case provides helpful context for discussion of the motions.

The Mitchells' complaint against Collagen was filed in state court on January 21, 1993. Collagen then removed the case to this court, and, on December 30, 1993, moved for summary judgment. Collagen asserts that all state law tort theories raised by the Mitchells' complaint are preempted by federal law.

On January 25, 1994, before responding to the summary judgment motion, the Mitchells moved for leave to amend their complaint to add the Deceptive Consumer Sales Act claim. The Mitchells contend that this claim is not preempted, even if all of their other claims are. Collagen immediately objected that the amendment would be futile, the amended complaint on its face showing the Deceptive Consumer Sales Act claim to be barred by the statute of limitations.

On February 17, 1994, the Mitchells filed their second motion to amend, an "amended" motion for leave to file an amended complaint. The purpose of the amended motion was to modify paragraph four of the proposed amended complaint to add the bracketed and italicized portion of the following quotation: "Plaintiffs were not reasonably able to discover or learn that there was a relationship between Defendant COLLAGEN CORPORATION'S products and her injuries until late 1991 [*,and due to the fraud and concealment of her causes of action by Collagen Corporation*]." The Mitchells explained that the purpose of this amendment was to make the amended complaint read as "more clearly setting out such fraud and/or fraudulent concealment on the part of Collagen Corporation, which tolls the statute of limitations under the [Deceptive Consumer Sales] Act."[1]

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[1] The quoted language is from "Plaintiff's Reply to Defendant's Objection to Motion for Leave to File Amended Pleading," filed on February 17, 1994. This document was stricken on Collagen's motion because untimely under this District's Local Rules.

Under Rule 15(a) of the FEDERAL RULES OF CIVIL PROCEDURE, the court must freely allow a complaint to be amended "when justice so requires." FED.R.CIV.P. 15(a); *DeSalle v. Wright*, 969 F.2d 273, 277-78 (7th Cir. 1992). It would be oxymoronic to suggest that justice "requires" that an amendment be allowed when the amendment would be futile. Thus, despite the liberality required by Rule 15(a), it is not an abuse of discretion to deny leave to make a futile amendment. *Id.* When the proposed amendment could not withstand a motion to dismiss, denying leave saves the defendant and the court needless work. *Perkins v. Silverstein*, 939 F.2d 463, 472 (7th Cir. 1991).

The Indiana Deceptive Consumer Sales Act contains a two-year **occurrence** statute of limitations: "Any action brought under this chapter may not be brought more than two years after the occurrence of the deceptive act . . .." Ind. Code § 24-5-.5-5(b). Because the statute unambiguously commences the limitations period on an "occurrence" rather than "accrual" of the cause of action, the period runs from that occurrence regardless whether the resultant damage can be ascertained. *See Havens v. Ritchey*, 582 N.E.2d 792, 794 (Ind. 1991) (construing similar statute of limitations in Indiana Medical Malpractice Act); *Weinberg v. Bess*, 638 N.E.2d 841, 844 (Ind. Ct. App. 1994) (for medical malpractice, "two-year period begins to run at the occurrence of the negligence rather than at the time the negligence is discovered").

Thus, the statute of limitations began to run in the present case, at the latest, on September 22, 1988, when Barbara Mitchell received her last injection -- her last "purchase" of Collagen's product -- not in late 1991 at the time she alleges she discovered that her injuries were related to the product. The two-year statute thus expired September 22, 1990, making her complaint filed January 21, 1993, appear untimely. It is this untimeliness that makes the Mitchells' attempt to add an

allegation of fraudulent concealment important.

The statute of limitations in the Deceptive Consumer Sales Act is subject to the equitable doctrine of fraudulent concealment, which estops a defendant who has actively deceived a plaintiff from asserting the defense.[2] *Cwiakala v. Economy Autos, Ltd.*, 587 F. Supp. 1462, 1466 (N.D. Ind. 1984). Thus, taking the allegations of the Mitchells' proposed amended complaint as true, Collagen's fraudulent concealment tolled the running of the two-year statute until late 1991 when the Mitchells learned of Collagen's (alleged) responsibility for her injuries.

The tolling of the limitations period until that time, however, did not allow the Mitchells a fresh two-year period in which to file their complaint. Instead, because "equity supplies what equity requires," their cause of action had to be commenced within a reasonable time. *Cacdac v. Hiland*, 561 N.E.2d 758, 759 (Ind. 1990) (medical malpractice); *O'Neal v. Throop*, 596 N.E.2d 984, 988 (Ind. Ct. App. 1992) ("two-year statute of limitations does not apply under the doctrine of fraudulent concealment . . . Instead, a plaintiff claiming fraudulent concealment has a duty to bring the action within a reasonable time after discovering the malpractice.")

Because malpractice actions are (or at least are perceived to be) relatively common and an injury from malpractie often becomes apparent only later, the determination whether a plaintiff relying on fraudulent concealment to toll the limitations period has commenced his/her action in a reasonable time comes up there often. The following periods of delay have been held unreasonable as a matter of law: twenty-two months, *Cacdac*,

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[2] When a fiduciary or confidential relationship exists, passive failure to disclose will suffice. *Hughes v. Glaese*, 637 N.E.2d 822, 825 (Ind. Ct. App. 1994).

561 N.E.2d at 759 ("delay of twenty-two months . . . was not reasonable . . . trial court should have granted Dr. Cacdac summary judgment"); thirteen months, *Babcock v. Lafayette Home Hospital*, 587 N.E.2d 1320, 1324-25 (Ind. Ct. App. 1992); twenty-one months, *Yarnell v. Hurley*, 572 N.E.2d 1312, 1315 (Ind. Ct. App. 1991); twenty-two months, *Cyrus v. Nero*, 546 N.E.2d 328, 331 (Ind. Ct. App. 1989); seventeen months, *Basinger v. Sullivan*, 540 N.E.2d 91, 95 (Ind. Ct. App. 1989); twenty-two months, *Spoljaric v. Pangan*, 466 N.E.2d 37, 45 (Ind. Ct. App. 1984).

In the present case the Mitchells have pleaded that they became aware of the linkage between Collagen's product and Barbara Mitchell's injuries late in 1991. Even though they filed a complaint approximately thirteen months later in January, 1993, they waited twelve more months, until January, 1994, before trying to bring their Deceptive Consumer Sales Act claim, *i.e.*, at least twenty-five months after discovering the connection to Collagen. This twenty-five month delay was unreasonable. Even if it could be argued that the January, 1994, proposed amendment should "relate back" -- an argument that the court finds unappealing -- to the January, 1993, filing, making the delay only thirteen months, even that delay would be unreasonable. Thus, because it is clear that the Mitchells' Deceptive Consumer Sales Act claim is barred by the statute of limitations, their attempt to add that claim to their complaint is futile, and both of their motions for leave to amend their complaint are **DENIED**.[3]

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[3] The Mitchells have not argued that Ind. Code § 34-1-2-9 (statutory extension of statute of limitations for fraudulent concealment) applies to commence a new two-year period beginning in late 1991, so the court need not decide that issue. In *Guy v. Schuldt*, 236 Ind. 101, 138 N.E.2d 891, 893 (Ind. 1956), the Indiana Supreme Court ruled that § 34-1-2-9 did not provide an exception to the later-enacted special

Collagen's Motion for Summary Judgment

Collagen contends that all of the state law causes of action the Mitchells assert are preempted by federal law, thereby entitling Collagen to a judgment of dismissal with prejudice. Alternatively, Collagen contends that as to any claims which are not preempted, the Mitchells have rested on their complaint and have no evidence in support of such claims, entitling Collagen to summary judgment.

Zyderm and Zyplast are classified by the Food and Drug Administration ("FDA") as "Class III medical devices" extensively regulated under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-395, more specifically, pursuant to the Medical Device Amendments of 1976 ("MDA") thereto, 21 U.S.C. §§ 360c-360l. As explained in both *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, -- U.S. -- , 114 S. Ct. 86, 126 L. Ed. 2d 54 (1993), and *King v. Collagen Corp.* 983 F.2d 1130 (1st Cir.), *cert. denied*, --U.S. --, 114 S. Ct. 86, 126 L. Ed. 2d 54 (1993), the MDA requires that medical devices undergo a rigorous premarket approval ("PMA") process to ensure their safety and efficacy before they can be dispensed to the public.

The MDA prohibits states from subjecting a medical device to "any requirement (1) which is different from, or in addition to, any requirement applicable under the [Food, Drug and Cosmetic Act] to the device, and (2) which relates to the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device under" the Act. 21 U.S.C. § 360k(a). In *Stamps* and *King* the Fifth and Fourth

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statute of limitations for medical malpractice actions. Giving that decision a hasty look, the Court's reasoning seems equally applicable here.

Circuits have agreed with Collagen's stance that this Provision preempts state tort claims like those the Mitchells have pleaded. The Mitchells respond that both decisions are "patently incorrect" and should not be followed by this court.

There is both a short and long answer to the preemption question debated by the parties. The short answer is that the court agrees with the result reached in *Stamps* and *King*. In § 360k(a) Congress expressly defined the preemptive reach of the MDA, so courts need only identify the domain created by the statutory language.[4] *Cipollone v. Liggett Group, Inc.*, -- U.S. --, 112 S. Ct. 2608, 2618, 120 L. Ed. 2d 407 (1992); *American Agriculture Movement v. Board of Trade*, 977 F.2d 1147, 1154 (7th Cir. 1992). *Stamps* and *King* correctly conclude that Congress, by using the phrase "any requirement," meant for the preemption provision to "sweep broadly" precluding not only positive enactments but also common-law tort actions.[5] *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993) (*Cipollone* "held that sweeping congressional efforts to pre-empt state regulation also bar state damages claims"); *Stamps*, 984 F.2d at 1421; King, 983 F.2d at 1134-35. The Court of Appeals explains:

> If the FDA in a valid regulation under the Medical Device Amendments requires X, and X relates to safety or effectiveness, a state cannot, whether through statute,

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[4] Justices Blackmun, Kennedy and Souter concurring in Section IV of the plurality opinion result in a majority for this proposition. *Vango Media Inc. v. New York City*, 34 F.3d 68 (2d Cir. 1994).

[5] The FDA is of the same view, declaring that preemption applies equally to "statute, ordinance, regulation, or court decision." 21 C.F.R. § 808.1(b).

regulation, or common law decision, require non-X or X + Y.

Slater v. Optical Radiation Corp., 961 F.2d 1330, 1333 (7th Cir.), *cert. denied*, -- U.S. --, 113 S. Ct. 327, 121 L. Ed. 2d 246 (1992).

The PMA process -- the validity of which the Mitchells do not question -- is without doubt an FDA regulation of this nature: a medical device categorized as a Class III device is subject "to premarket approval to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). As the Mitchells admit in opposing summary judgment, this requirement is not substantially different from "state tort products liability and similar actions requiring reasonable product safety and effectiveness." Plaintiffs' Brief, p. 10.[6] These state tort actions are therefore requirements in addition to the PMA process, and preempted. *Stamps*, 984 F.2d at 1423-24. "The plaintiff wishes in the name of state tort law to impose additional requirements . . . and this engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Device Amendments." *Slater*, 961 F.2d at 1333. Effectively, the MDA causes blanket preemption.[7] This short answer is less than completely

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[6] All references to "Plaintiffs' Brief" are to "Plaintiffs' Response in Opposition to Defendant's Motion for Summary Judgment and Memorandum of Authorities," filed January 28, 1994.

[7] *Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1437 (C.D. Cal. 1994) concludes that "the First and Fifth Circuits, and numerous district courts, with one exception, have followed a rule of blanket preemption [under the MDA] for Class III devices." The court lists the cases it surveyed to reach this conclusion. 858 F. Supp. at 1437 n. 17. *Shiley*, reaching a different result, appears to become the second

satisfactory. It does not explain why the court rejects the Mitchells' arguments that *Stamps* and *King* were wrongly decided. It also does not explain why the court, unlike *Stamps*[8] and *King*, has not followed the approach recommended by the *Cipollone* plurality, inquiring tort-by-tort whether the tort's underlying duty relates to safety and effectiveness. 112 S. Ct. at 2621. The court therefore will address each of the Mitchells' arguments, and in so doing, attempt to explain where it parts company with *Stamps* and *King*. The arguments are addressed in the order made in the Plaintiffs' Brief.[9]

1. Initial Preemption Determination

First, the Mitchells argue that the MDA does not preempt state law unless the FDA first determines that the particular state law requirement in question is preempted. Because the MDA preempts only state law requirements which are "different from, or in addition to" federal requirements,[10] 21 U.S.C. §

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exception. As discussed *infra* at p. 23 n. 18, the court respectfully disagrees with *Shiley*.

[8] *Stamps* does not categorically analyze each cause, but only because it relies on a prior decision, *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989), which did. *Stamps*, 984 F.2d at 1422.

[9] Because the court has denied the Mitchells' request to amend their complaint to add a cause of action under the Indiana Deceptive Consumer Sales Act, the court does not address their arguments that this cause would not be preempted.

[10] This is a fine example of drafting overkill making a statute less than clear. If only different or additional requirements are preempted, then only identical requirements are not preempted (because lesser requirements would be preempted as different). Does it matter

360k(a), the Mitchells believe the following (as misquoted by them) portion of 21 C.F.R. § 808.1(e) sets out a prerequisite to preemption: "It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, such requirements. . ." The Mitchells believe that until the FDA makes this determination after being requested by an "interested person" to issue an advisory opinion as to preemption pursuant to 21 C.F.R. § 808.5(a), the MDA has no preemptive effect and a court ruling otherwise would "usurp the FDA's authority." Plaintiffs' Brief, p. 4.

This argument is untenable, and can be made only by divorcing the misquoted regulation from its context. The MDA allows states and their governmental units to apply to the FDA for exemption of state law from preemption. 21 U.S.C. § 360k(b). Accordingly, the FDA has promulgated regulations "for the submission, review, and approval of applications for exemption from Federal preemption . . .." 21 C.F.R. § 808.1(a). It is only in the context of these regulations that the FDA has a responsibility to determine whether state requirements differ from federal requirements: this determination, rather than being a prerequisite to preemption, is necessary only because the statute itself preempts different or additional state requirements.

This is clear not only from viewing part 808 as a whole but merely from reading the complete text of § 808.1(e), as opposed to the sentence fragment (mis)quoted by the Mitchells:

> It is the responsibility of the Food and Drug Administration, subject to review by Federal Courts, to

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one whit that identical requirements are not preempted? It would seem that where state and federal requirements are identical, compliance with either would satisfy both, making the preemption issue irrelevant.

> determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. **However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any state or political subdivision whose requirements relating to devices are preempted by section [360k(a)]** may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(Emphasis added). It is plain that § 360k(a) of the MDA causes immediate preemption whenever state and federal requirements are inconsistent, otherwise, there would be no initial burden on the states to decide whether to seek an exemption.

Thus, the procedure for obtaining an advisory opinion, rather than being the catalyst for preemption, allows an "interested person" to determine whether a state requirement can safely be ignored, and a state to determine whether its requirements are enforceable or there is a need to seek an exemption from preemption. This interpretation makes sense of the following aspect of the procedure for obtaining an advisory opinion: "The [FDA] . . . after consultation with the State or political subdivision, may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under § 808.20." This provision presupposes that the MDA causes preemption to occur before an advisory opinion is obtained. Were it otherwise, as the Mitchells argue, a state could not benefit by requesting an advisory opinion, but instead only suffer the undesired consequence -- preemption of a state regulation.

2. FDA Opinions that General State Tort Law not Preempted

The Mitchells' second argument is that the FDA has already determined that the MDA preempts only state tort law requirements directed specifically at medical devices, not tort law of general applicability. The Mitchells have attached what appear[11] to be copies of two FDA advisory opinions, dated March 8, 1984, and February 2, 1988, which take that position. The 1988 letter states in part that "it is the Food and Drug Administration's (FDA) position that section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360(k)) preempts only state and local requirements that are specifically related to medical devices." Citing *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 105 S. Ct. 2371, 85 L. Ed. 2d 714 (1985), the Mitchells argue that the FDA's position is dispositive.

This is simply not true, and the Mitchells ignore that part of their cited authority that contradicts their position. In *Hillsborough County* the Supreme Court did not, as the Mitchells citation suggests, hold that an agency determination is dispositive. Instead, the Court stated "the FDA's statement is dispositive . . . unless . . . the agency's position is inconsistent with clearly expressed congressional intent . . ." *Hillsborough County*, 471 U.S. at 714, 105 S. Ct. at 2376.

The FDA's interpretation that the MDA preempts only state requirements directed specifically at medical devices is contrary to the intent expressed in the statute, considering the Supreme Court's interpretation of similar language in other statute's preempting state law. The MDA preempts any state law which "relates to" safety and effectiveness. 21 U.S.C. § 360k(a). The Supreme Court has held that when Congress chooses "relating

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[11] Collagen has not objected to the documents' authenticity.

to" phraseology in a preemption provision, it intends the provision to sweep expansively. *Morales v. Trans World Airlines*, 504 U.S. 374, 112 S. Ct. 2031, 119 L. Ed. 2d 157 (1992).

In an analogous context the Court in *Morales* rejected the cramped definition of "relating to" that the FDA has adopted in respect to the MDA:

> [P]etitioner advances the notion that only State laws specifically addressed to the airline industry are preempted, whereas the [Airline Deregulation Act] imposes no constraints on laws of general applicability. Besides creating an utterly irrational loophole . . ., this notion similarly ignores the sweep of the 'relating to' language. We have consistently rejected this precise argument in our ERISA cases: '[A] state law may 'relate to' a benefit plan, and thereby be preempted, even if the law is not specifically designed to affect such plans, or the effect is only indirect.'

Morales, 112 S. Ct. at 2038 (citations omitted).

The "precise argument" rejected by the Supreme Court -- that a law of general applicability does not "relate to" a specific subject area -- is the position the FDA has taken in interpreting the MDA. Because such an interpretation is contrary to the clearly expressed intent of Congress, the court gives it no deference. *Dole v. United Steelworkers of America*, 494 U.S. 26, 42, 110 S. Ct. 929, 938, 108 L. Ed. 2d 23 (1990).

3. The Indiana Attorney General Opposes MDA Preemption

The Mitchells' third argument is that Pamela Carter, Indiana's Attorney General, has publicly opposed preemption of state tort law by the MDA, when Indiana joined in an *amici curiae* brief seeking *certiorari* in *Stamps* and *King*. The

Mitchells ask the court to consider the arguments made in the *amici curiae* brief.

Preemption doctrine results from the dual between sovereigns inherent in a federal system. Whether a statute Congress enacts preempts state law depends on Congress' intent as expressed in the statute, not on whether a state agrees that its laws are, or should be, preempted. For this reason, and because the court does not sanction the practice of adopting by reference briefs from other cases, this argument does not merit further discussion.

4. Proposed Legislation Shows the MDA did not Preempt State Law

The Mitchells' fourth argument is that Congress does not view the MDA as having preempted state tort law. Proposed legislation introduced October 13, 1993, "The Comprehensive Family Health Access and Savings Act," contained a provision prohibiting an award of punitive damages against the manufacturer of a medical device. As this provision would be unnecessary if the MDA preempts state tort law, the Mitchells' argument is not implausible. As proposed legislation, however, this at best demonstrates the understanding of the act's sponsors, not Congress. Even given broader due, as the plurality noted in *Cipollone* "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *United States v. Price*, 361 U.S. 304, 313, 80 S. Ct. 326, 332, 4 L. Ed. 2d 334 (1960); *Cipollone*, 112 S. Ct. at 2619.

Most important, in *Cipollone* the Court held that an express preemption provision in a statute confines judicial determination of the statute's preemptive reach to construction of that provision. 112 S. Ct. at 2618; *see also N.A.A.C.P. v. American Family Mutual Insurance Co.*, 978 F.2d 287, 294 (7th Cir. 1992) ("We must determine what Congress meant *by what it*

enacted, not what Senators and Representatives said, thought, wished or hoped.") As a result, it would be improper for this court to interpret § 360k(a) of the MDA by divining legislative intent from the provisions of unenacted legislation considered by a subsequent Congress.

5. The MDA Does Not Preempt General State Tort Law

Fifth, the Mitchells contend that state tort laws of general applicability (i.e., not applicable only to medical devices) are not preempted. They first point to 21 C.F.R. § 808.1(d)(1) which states exactly this proposition: "Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes and the Uniform Commercial Code (warranty of fitness)) . . . ".

This is a retread of their second argument, which relied on FDA advisory opinions to make the point, but with different evidence of how the FDA interprets the statute. Thus, the court need only reiterate that this interpretation is contrary to the Congress's intent, as expressed in the § 360k(a) of the MDA, and so the FDA regulation is entitled to no deference.[12] *Dole*,

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[12] The FDA's conclusion that requirements of general applicability are not preempted appears to derive from its view that such requirements "are not preempted by section 521(a) [§ 360k(a)] because they are not 'requirements applicable to a device' within the meaning of section 521(a) of the act . . ." 21 C.F.R. § 808.1(d). Oddly, § 360k(a) does not contain the phrase the FDA places in quotation marks.

Instead, the word "applicable" appears only in the following context: ". . . no State . . . may establish or continue in effect with respect to a device . . . any requirement -- (1) which is different from, or

494 U.S. at 42, 110 S. Ct. at 938.

Continuing with additional support for the proposition that general tort laws are not preempted, the Mitchells argue that preemption occurs only after the FDA establishes "specific counterpart regulations . . . making any existent divergent state or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements." 21 C.F.R. § 808.1(d). The Mitchells insist that there are no FDA regulations applicable to Zyderm and Zyplast which are "specific counterpart regulations" to state tort law. In other words, the federal PMA process would preempt only a similar state PMA process. The Mitchells rely on *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 1, 837 P.2d 1273 (1992), which held that the PMA process is a mere procedural requirement, not a regulation of safety and effectiveness, and thus does not trigger preemption.

That view does not find support in this circuit, however. Considering the preemptive effect of procedural, as opposed to substantive, MDA requirements for experimental devices, the Court of Appeals observed that such regulations "specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect." *Slater*, 961 F.2d at 1333. Similarly, the PMA process, while procedural, is designed to require manufacturers of medical devices to determine and demonstrate that the devices are safe and effective before obtaining approval to market. The court

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in addition to, **any requirement applicable under this chapter** to the device . . ." 21 U.S.C. § 360k(a) (emphasis added.) The phrase "with respect to a device" appears to limit preemption only by meaning that state requirements are not voided: they continue in effect insofar as they apply to anything other than medical devices.

therefore agrees with *Stamps* that once the FDA imposes any requirement upon a device -- PMA being a requirement -- state tort causes of action relating to safety and effectiveness are preempted.[13] *Stamps*, 984 F.2d at 1423-24.

The Mitchells' final effort to support their "no preemption of general law" argument is based on the FDA's construction of the phrase "different from, or in addition to" used in § 360k(a) of the MDA. The FDA sensibly believes this phrase as meaning that state requirements that are "substantially identical to" federal requirements are not preempted. 21 C.F.R. § 808.1(d)(2). In an attempt to attach meaning to this irrelevancy, see n. 10 at p. 10, *supra*, the FDA defines "substantially identical to" to include any state requirement that "does not significantly differ in effect from a Federal requirement." 21 C.F.R. § 808.3. It is not difficult to conclude then, as the Mitchells do, that state tort laws are not preempted because they do not differ "in effect" from the PMA -- both having the effect of requiring medical devices to be safe and effective.

The Mitchells' analysis is sound: the FDA'S definition of "substantially identical to" is not. The plain language of the MDA preempts additional or different state requirements relating to safety and effectiveness, whether or not they have the same "effect" as the federal requirements. For example, 21 C.F.R. § 801.430(f) specifies the absorbency test to be used for menstrual tampons. A state law requiring a different test but with the same effect -- determining absorbency -- would nevertheless be preempted.[14]

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[13] *Stamps* also points out that *Larsen* is distinguishable because it involved a "substantially equivalent" device which underwent a less rigorous PMA than a new device. *Stamps*, 984 F.2d at 1423 n.6.

[14] Making this point further, a manufacturer can use a different absorbency test only by demonstrating equivalency and obtaining FDA

And so it is with state tort laws. While they may have the same effect as the PMA process, safety and effectiveness, they achieve that effect only by imposing different or additional requirements on devices: *e.g.*, different or additional premarket testing should have been done, the device literature should have contained additional or different warnings. "[T]his engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Device Amendments." *Slater*, 961 F.2d at 1333.

6. Plaintiffs' Claims not Preempted Under Cipollone Analysis[15]

The Mitchells argue that applying the preemption analysis used by the Supreme Court in *Cipollone*, the MDA does not preempt their breach of warranty, fraud and misrepresentation claims. *Stamps* and *King*, both coming to a contrary conclusion, are accordingly erroneous and should not be followed. In order to address this argument the court first explains its understanding of the badly fractured decision in *Cipollone*, and the adherence of *Stamps* and *King* thereto.

In *Cipollone* the Court addressed the issue of the scope of preemption under the Public Health Cigarette Smoking Act of 1969, which preempts any "requirement or prohibition based on smoking and health . . . imposed under State law . . .". 15 U.S.C. § 1334(b). While six of the nine Justices agreed that a "requirement or prohibition" includes state common law tort

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approval. 21 C.F.R. § 801.430(f)(3).

[15] In the first portion of this argument plaintiffs reiterate for the third time that 21 C.F.R. § 808.1(d)(1) excludes tort laws of general applicability from preemption. In addressing plaintiffs' second and fifth arguments the court has explained why it rejects that FDA interpretation of the MDA's preemptive scope.

causes, no majority agreed on how to determine whether a tort requirement is "based on smoking and health."[16]

A plurality of four Justices decided that the answer depends on whether the "legal duty that is the predicate of the common law damages action" is "based on" smoking and health. 112 S. Ct. at 2621. Thus, the plurality concluded that a fraud claim based on advertisements containing false statements of fact would not be preempted because "not predicated on a duty 'based on smoking and health' but rather on a more general obligation--the duty not to deceive." *Cipollone,* 112 S. Ct. at 2624. On the other hand, failure-to-warn claims (related to advertising and promotion) were held preempted, and thus implicitly found to be based on smoking and health. *Id.* at 2621-22.

Justice Blackmun, joined by Justices Kennedy and Souter, of the view that the statute did not preempt state common-law damages actions at all, dissented from the plurality's "little short of baffling" conclusion that some common-law tort causes of action were preempted, and thus from the court's judgment to that extent.[17] *Id.* at 2627, 2631. Moreover, in dissenting the

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[16] Prior to amendment in 1969, instead of "based on" the statute used the phrase "relating to smoking and health" -- very similar to the MDA's "relates to the safety and effectiveness." In commenting on the effect of Congress having amended the wording, the plurality observed that "the phrase 'relating to smoking and health' . . . was essentially unchanged by the 1969 Act. . .". *Cipollone,* 112 S. Ct. at 2624.

[17] The Justices concurred with the plurality's opinion to form a majority for the following propositions: 1) the preemptive scope of a statute must be determined entirely from the express language used in its preemption provisions, *Id.* at 2625; 2) state common-law damages claims are not preempted unless the statutory language chosen by

Justices took the plurality to task for focusing its analysis on the legal duty serving as the predicate of the tort. Justice Blackmun found the analysis's "most obvious problem . . . its frequent shift in the level of generality at which it examines individual claims." *Id.* at 2631.

As an example of this shift, Justice Blackmun pointed to the plurality's conclusion that failure to warn claims were preempted, but fraudulent misrepresentation claims were not, because based on a general duty not to deceive. Justice Blackmun objected that the failure-to-warn claims "could just as easily be described as based on a 'more general obligation' to inform consumers of known risks" and thus found not preempted. Justice Blackmun viewed the plurality's approach as creating "a crazy quilt of pre-emption," concluding:

> In short, I can perceive no principled basis for many of the Court's asserted distinctions among the common-law claims, and I cannot believe that Congress intended to create such a hodge-podge of allowed and disallowed claims . . . I can only speculate as to the difficulty lower courts will encounter in attempting to implement the Court's decision.

Id. at 2631.

Justice Scalia, joined by Justice Thomas, agreed with Justice Blackmun's critique of the plurality's approach, describing it as "suspect, to begin with, because the plurality is unwilling to apply it consistently." *Id.* at 2636. Justice Scalia proposed an alternative: "Once one is forced to select a *consistent*

Congress indicates a clear and manifest purpose to do so, *Id.* at 2626, and; 3) the 1965 Federal Cigarette Labeling and Advertising Act does not preempt state common-law damages claims. *Id.*

methodology for evaluating whether a given legal duty is 'based on smoking and health', it becomes obvious that the methodology must focus not upon the ultimate source of the duty (*e.g.*, the common law) but upon its proximate application." *Id.* To apply this test, Justice Scalia "would ask . . . whether, whatever the source of the duty, it imposes an obligation in this case because of the effect of smoking upon health," and would have concluded in the case before the Court that all of the tort claims raised were preempted. *Id.* at 2637.

This effort to explain the Justices' diverging opinions is of more than pedantic interest: when no opinion commands the support of a majority of the Justices, the task of this court is to determine the court's holding by finding the narrowest ground upon which those concurring with the plurality agree, i.e., the "lowest common denominator" holding. *Marks v. United States*, 430 U.S. 188, 193, 97 S. Ct. 990, 993, 51 L. Ed. 2d 260 (1977); *Cygnar v. City of Chicago*, 865 F.2d 827, 838 (7th Cir. 1989); *Janowiak v. City of South Bend*, 836 F.2d 1034, 1041 (7th Cir. 1987); *Britton v. South Bend Community School Corp.*, 819 F.2d 766, 768 (7th Cir. 1987); *Schindler v. Clerk of Circuit Court*, 715 F.2d 341, 345 n. 5 (7th Cir. 1983).

While Justices Scalia and Thomas votes created a majority for the court's judgment that state law tort claims "based on smoking and health" were preempted, there is no narrow ground of agreement on the method for making that determination. To the contrary, as just explained above, a majority of five Justices agreed that the plurality's "ultimate source" analysis was flawed and unworkable. Thus, there is no lowest common denominator holding instructing lower courts how to determine when a tort requirement is "based on" or "relates to" something else -- in this case, safety and effectiveness -- and is preempted. *Cf. Schindler*, 715 F.2d at 345, n. 5.

Returning to the Mitchells' argument, they believe that if *Stamps* and *King* had faithfully followed *Cipollone*, the

decisions would have found breach of warranty, fraud and misrepresentation claims not preempted by the MDA. The unacknowledged premise of this argument is that the *Cipollone* pluarlity's "ultimate source" analysis is a holding which must be followed.[18] That premise, which finds some support in *Stamps*, 984 F.2d at 1422, and, to a lesser degree, *King*, is both unfounded and suspect. As explained above, unfounded because the analysis is not a "least common denominator" agreed to by a majority of the Justices; suspect because, as *Stamps* and *King* both recognize, *Cipollone* does suggest that fraud and breach of warranty claims are not preempted.

Stamps and *King* both somewhat uncomfortably reach the opposite result, however. For example, in finding the fraud claims at issue preempted by the MDA, Stamps read the complaint as having pleaded fraud inadequately, instead sounding in negligence. *Stamps*, 984 F.2d at 1422 n. 5. *King* read the complaint's fraud claim as having been originally based on a statute requiring privity, despite plaintiff's insistence the claim (like that in *Cipollone*) was based on a general duty not to deceive. *King*, 983 F.2d at 1136.

Neither distinction is compellingly persuasive, particularly in this circuit where a "complaint need not identify a legal theory, and specifying an incorrect theory is not fatal." *Bartholet v.*

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[18] This is the approach taken in what appears to be the most recent case addressing the scope of preemption under the MDA, *Ministry of Health v. Shiley*, 858 F. Supp. 1426 (C.D. Cal. 1994). *Shiley* concludes that *Cipollone* requires that "state claims against Class III device manufacturers survive if the legal duty underlying the state claim either has a basis independent of the MDA's focus on the medical device's safety and effectiveness, or arises from the manufacturer and not from the state." 858 F. Supp. at 1440. For the reasons explained in this order, the court respectfully disagrees with *Shiley*.

Reishauer A.G. (Zurich), 953 F.2d 1073, 1078 (7th Cir. 1992). The court believes that *Stamps* and *King* both reached a correct result, however, and one that can easily be supported simply by applying the "proximate application" methodology proposed by Justice Scalia. 112 S. Ct. at 2636-37. Because the court does not read *Cipollone* as providing a holding that requires otherwise, and because the court believes it the better and more consistent of the two approaches, the court will apply the "proximate application" methodology to the Mitchells' tort causes of action.

To apply Justice Scalia's proximate application methodology in the present circumstances, the court simply inquires whether the tort imposes an obligation that relates to the safety and effectiveness of Zyderm and Zyplast, no matter where the source of the tort's duty lies. Considering this as the relevant inquiry with respect to each of the Mitchells' tort claims -- at least those for which there is evidentiary support creating a factual dispute sufficient to withstand summary judgment -- the court finds all preempted.

As to fraud and misrepresentation, the Mitchells' claim takes two avenues. First, that Collagen obtained the FDA's approval to market Zyderm and Zyplast through fraud and misrepresentation in the PMA process. Second, that Collagen continues to market the devices through fraud and misrepresentation.

As to fraud in the PMA process, the Mitchells claims, even if not preempted, fail for lack of proof. The Mitchells have not disputed Collagen's evidence that the FDA has comprehensively reexamined its original decision to approve Collagen's PMA application and reaffirmed that decision. The Mitchells have merely rested on their pleadings, failing to come forward with any proof of the fraud they allege. When opposing a motion for summary judgment, a party who has the burden of proof may

not rest on the allegations of their pleadings.[19] *Chambers v. American Trans Air, Inc.*, 17 F.3d 998, 1002 (7th Cir. 1994).

Moreover, the evidentiary problem aside, this fraud claim would require the Mitchells to prove that more, or different, information should have been provided to the FDA as part of Collagen's PMA application, causing the FDA to reach a different decision. Thus the torts would impose additional obligations relating to safety and effectiveness and are preempted. *King*, 983 F.2d at 1136, 1140.

Similarly, with respect to the Mitchells' claims that Zyderm and Zyplast are marketed through fraud and misrepresentation, "if the MDA does nothing else, it regulates the . . . sale and marketing of Class III medical devices in an extensive way. The MDA does this through the packaging and labeling requirements which directly affect the marketing and sale of the product." *King*, 983 F.2d at 1136. Thus, the Mitchells' claims with respect to fraud in advertising would impose additional requirements and are preempted.

As to breach of warranty claims, the court agrees with *King* that the MDA is not like the statute addressed in *Cipollone*, which did not restrict the ability of cigarette manufacturers to make warranties in their advertising and promotion. Instead, all aspects of product labeling and literature are regulated by the FDA under the MDA, preventing Collagen from making any

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[19] After the briefing had closed on Collagen's motion for summary judgment, the Mitchells, for the first time, moved for a continuance in order to conduct discovery to support their response. This effort, made nearly two months after responding to Collagen's motion (after being allowed an extension of time to make that response), comes too late. The Mitchells chose to respond to the motion instead of utilizing RULE 56(f) to first obtain the discovery (allegedly) needed. As a result, the motion is ruled on as briefed. *Chambers*, 17 F.3d 1002.

warranties that are not FDA approved. *King*, 983 F.2d at 1135. Thus, a breach of warranty cause of action would impose different or additional requirements with respect to safety and efficiency, and is preempted.

As to their failure to warn and insufficient warning claims, the Mitchells contend (and Collagen admits) that under the MDA a device manufacturer can add additional safety warnings to product labels without prior FDA approval. 21 C.F.R. § 814.39. Thus, the Mitchells argue that state tort law that would require those changes is consistent with the MDA and not preempted. This argument fails to observe the distinction between allowing an act and requiring that act. The MDA allows, but does not require, the manufacturer to change its label.[20] Requiring the manufacturer to do so via a failure to warn claim would impose an additional requirement with respect to safety, and such a tort is therefore preempted by the MDA. *Stamps*, 984 F.2d at 1424.

Finally, the Mitchells assert that their claims of product mislabeling, misbranding and adulteration are not preempted. In the court's view the Mitchells admit that these claims are the same as their claims of fraud and misrepresentation in product labeling (i.e., the products are misbranded or mislabeled because they were not safe and effective when used in accordance with their labeling), Plaintiffs' Brief, p. 13, and, as explained above, such claims are preempted. *King*, 983 F.2d at 1136.

To the extent that the Mitchells claim is that the products

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[20] The Mitchells cite 21 C.F.R. § 201.57(e) as authority requiring Collagen to add a warning to product labeling as soon as evidence of an association with a serious hazard exists. The cited regulation applies to drugs, not products, although the Mitchells' attorneys represent otherwise in quoting it by deleting a reference to drug and replacing it with "[product]." Plaintiffs' Brief contains a disturbing number of similar examples of misleading quotations.

were adulterated, *i.e.*, were not the products approved by the FDA as described in Collagen's PMA application, the Mitchells, as with their claims of fraud in the application for premarket approval, have simply rested on their pleadings. Thus, these claims, even if not preempted, fail because the Mitchells have pointed to no evidence of adulteration upon which they could go to a jury.

Because plaintiff Barbara Mitchell's claims are decided against her on the merits, the derivative claim of her spouse, plaintiff Gregory Mitchell, for loss of consortium, is not viable. *Board of Commissioners of Cass County v. Nevitt*, 448 N.E.2d 333, 341 (Ind. Ct. App. 1983). Collagen is therefore entitled to summary judgment thereon.

CONCLUSION

As explained in this overly-lengthy order and memorandum opinion, the court **DENIES** the Mitchells' motions to amend their complaint. The court finds that the state common law tort causes of action pleaded by the Mitchells are either unsupported by any evidence creating an issue of fact upon which the issue could be submitted to a jury, or are preempted by the MDA. As a result, Collagen's motion for summary judgment is **GRANTED**. The clerk shall enter a final judgment in favor of defendant Collagen Corporation, plaintiffs Barbara and Gregory Mitchell to take nothing by their action. Costs of action as allowed by RULE 54(d).

SO ORDERED.

In the
United States Court of Appeals
For the Seventh Circuit

No. 94-3946

BARBARA MITCHELL and GREGORY MITCHELL,
Plaintiffs-Appellants,

v.

COLLAGEN CORPORATION,
Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Indiana, Hammond Division.

No. 93 C 283--James T. Moody, Judge.

ARGUED MAY 19, 1995--DECIDED OCTOBER 2, 1995

Before CUDAHY, RIPPLE and KANNE, Circuit Judges.

RIPPLE, Circuit Judge. In this case, Barbara and Gregory Mitchell appeal the district court's decision denying them leave to amend their complaint and dismissing their state law claims on the ground that they were all preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c-360l. For the reasons that follow, although we conclude that some state law claims are not preempted by the MDA, we affirm the judgment of the district

court.

I
BACKGROUND

A. *Facts*

In 1988, Barbara Mitchell received several injections of Zyderm or Zyplast (collectively, "Zyderm"), collagen-based products produced by Collagen Corporation. These products are used to correct skin tissue anomalies such as wrinkles. Under the Medical Device Amendments, 21 U.S.C. § 360c-360l (MDA), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-395, Zyderm is classified as a "Class III medical device." Class III devices must be approved by the FDA before they may be sold to the public. 21 U.S.C. § 360c(a)(1)(C).

The premarket approval ("PMA") process is used to determine "the safety and effectiveness" of a device with respect to its intended users under the conditions "prescribed, recommended, or suggested" in its labeling. 21 U.S.C. § 360c(a)(2). As part of the PMA process, a manufacturer must submit samples of the device, an outline of the device's components and properties, a description of the manufacturing process, safety data, a bibliography of all reports concerning the device's safety and effectiveness, copies of all proposed labeling, and any other information the FDA requests. 21 U.S.C. § 360e(c); *see also* 21 C.F.R. § 814.20. The application is referred to a panel of qualified experts for study and submission of a report and recommendation respecting approval. 21 U.S.C. § 360e(c)(2); *see id.* § 360c(b)(2) (describing composition of panels). The FDA retains the right to withdraw its approval if it finds that a device previously approved is not safe and effective. 21 U.S.C. § 360e(e).

Zyderm's PMA initially was approved in 1981. The FDA

approved the PMA for Zyplast, a derivative of Zyderm, in 1985. During 1991-1992, the FDA conducted a re-review of Zyderm and concluded in early 1992 that its PMA approval decision was appropriate.

B. *Earlier Proceedings*

Following her injections, Barbara Mitchell developed serious medical complications. In 1993, she and her husband filed suit against Collagen in Indiana state court. Their complaint included counts sounding in strict liability, negligence, fraud, mislabeling, misbranding, adulteration, and breach of warranty. Collagen removed the case to federal court. The Mitchells moved to amend their complaint to add a claim under Indiana's Deceptive Consumer Sales Act; Collagen filed for summary judgment on the ground that the Mitchells' claims were preempted by federal law.

The district court denied the Mitchells' motion for leave to amend. 870 F. Supp. 885, 887-89 (N.D. Ind. 1994). The court reasoned that amendment would be futile because the Mitchells' claim would be time-barred under the applicable limitations period. The district court further held that the Mitchells' claim was not saved by their allegation that Collagen had concealed fraudulently their claims. The court reasoned that, even if the Mitchells could rely upon a claim of fraudulent concealment to toll the applicable limitations period, such tolling would occur for only a "reasonable time." The court found the Mitchells' delay in filing suit unreasonable. It noted that the Mitchells knew that Zyderm was related to Barbara Mitchell's injuries since at least 1991 and that they had delayed thirteen months between the time they acquired this information and the time they first filed suit against Collagen, and an additional twelve months before they sought to add the Deceptive Consumer Sales Act claim.

Next, the court determined that the Mitchells' remaining

state law claims were preempted. 870 F. Supp. at 889-98. The court focused upon the MDA's preemption provision, which expressly proscribes states from establishing "any requirement . . . different from, or in addition to," the requirements established pursuant to the MDA. *See* 21 U.S.C. § 360k(a).[1] Regulations promulgated by the FDA explain that the state "requirements" preempted under section 360k(a) include those "established by statute, ordinance, regulation or court decision." 21 C.F.R. § 808.1(b). Relying upon the statutory preemption provision, the court reasoned that Congress intended the MDA amendments to have a broad preemptive effect--one that encompassed common law causes of action. It further reasoned that, in the case of Class III devices, the detailed premarket approval procedures constituted applicable federal requirements that preempted all state laws that established standards "different from, or in addition to," the federal mandates. To the extent that the FDA's regulations, such as 21 C.F.R. § 808.1(d),[2]

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[1] The statute provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

[2] The regulation provides, in pertinent part:

> State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other

suggested that the MDA amendments preempted only those state laws directed specifically at medical devices, the district court continued, they were inconsistent with congressional intent and entitled to no deference.

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specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by [21 U.S.C. § 360k(a)] because they are not 'requirements applicable to a device' within the meaning of section [360k(a)]. The following are examples of State and local requirements that are not regarded as preempted by section [360k(a)] of the act:

(1) Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

* * *

(6)(ii) Generally, section [360k(a)] does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, *e.g.*, a specific labeling requirement, then the prohibition will be preempted if it is different from, or in addition to, a Federal requirement established under the act.

21 C.F.R. § 808.1(d).

II

DISCUSSION

There are two basic issues on appeal. First, we must determine whether the district court erred in denying the Mitchells leave to amend their complaint. We review the district court's decision for abuse of discretion. *Cleveland v. Porca Co.*, 38 F.3d 289, 297 (7th Cir. 1994). Second, we must consider whether the district court properly granted Collagen summary judgment on the ground that the Mitchells' remaining state law claims were preempted. We review the district court's grant of summary judgment *de novo*. *Green v. Shalala*, 51 F.3d 96, 99 (7th Cir. 1995). Summary judgment is appropriate when there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. *Id.*; *see generally Doe v. R.R. Donnelley & Sons Co.*, 42 F.3d 439, 443-44 (7th Cir. 1994).

A. *Denial of Leave to Amend*

The Mitchells submit that the district court abused its discretion in denying their motion for leave to amend their complaint. Federal Rule of Civil Procedure 15(a) directs the district courts freely to allow leave to amend a complaint "when justice so requires." Fed. R. Civ. P. 15(a). However, district courts need not entertain futile amendments to the pleadings. *Moore v. State of Ind.*, 999 F.2d 1125, 1128 (7th Cir. 1993); *DeSalle v. Wright*, 969 F.2d 273, 278 (7th Cir. 1992). Thus, the district court does not abuse its discretion in denying leave to amend when the proposed amendment could not withstand a motion to dismiss. *See Bower v. Jones*, 978 F.2d 1004, 1008 (7th Cir. 1992) ("An amendment is futile when it . . . could not withstand a motion to dismiss."); *see also Moore*, 999 F.2d at 1128.

In this case, the Mitchells sought leave to add a claim against Collagen under the Indiana Deceptive Consumer Sales Act. Such claims are subject to a two-year occurrence limitations period. *See* Ind. Code § 24-5-0.5-5(b) ("Any action brought under this chapter may not be brought more than two (2) years after the occurrence of the deceptive act[.]"). Collagen notes that, in this case, the two-year period began to run no later than September 1988, when Barbara Mitchell received her final injection. Therefore, Collagen contends, the limitations period expired well before the Mitchells filed suit in 1993. The Mitchells respond, however, that Collagen should be stopped from raising the limitations period as a defense because Collagen fraudulently concealed their cause of action from them. Collagen replies that the Mitchells should not receive any equitable extension of the limitations period because their delay in seeking leave to amend was unreasonable.

Under Indiana law, when grounds such as fraudulent concealment exist for estopping a defendant from raising the expiration of the statute of limitations as a defense a limitations period may be extended in equity to allow a plaintiff a reasonable time within which to file suit. *See, e.g.; Babcock v. Lafayette Home Hosp.*, 587 N.E.2d 1320, 1324 (Ind. Ct. App. 1992). This equitable extension, however, does not resurrect the full limitations period for the plaintiff. Rather, it affords the plaintiff merely a "reasonable period" in which to file suit. *Id.; Yarnell v. Hurley*, 572 N.E.2d 1312, 1315 (Ind. Ct. App. 1991); *see also Cacdac v. Hiland*, 561 N.E.2d 758, 759 (Ind. 1990).

Applying these principles, we cannot say that the district court abused its discretion by denying the Mitchells leave to amend. The Mitchells rely on Collagen's alleged fraudulent concealment as the basis for seeking an extension of the applicable limitations period. However, the Mitchells' own complaint makes clear that they knew Collagen might be the source of their injuries by late 1991. *See* Complaint, R.1, Ex.A

at 3, Count I, para. 10 ("Plaintiffs Barbara and Gregory Mitchell learned that there was a relationship between Defendant Collagen Corporation's products and her injuries in the fall of 1991."). The Mitchells do not explain why they waited twenty-five months after first acquiring this knowledge, or, more particularly, over twelve months after first filing suit against Collagen, to seek leave to add their claim under the Indiana Deceptive Consumer Sales Act. Consequently, the district court did not abuse its discretion in denying leave to amend. The Mitchells' unexplained delay was not reasonable, and, therefore, there would have been no basis for extending the expired limitations period to save their time-barred claim. *Cf. Babcock*, 587 N.E.2d at 1324-25 (finding unreasonable plaintiff's unexplained failure to file suit until over one year after learning defendant had injured her).

B. *Preemption*

1.

We begin with a review of the principles that govern preemption analyses. Under the Supremacy Clause, "the Laws of the United States . . . shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Pursuant to this authority, the Congress may preempt state law. *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 368 (1986). "Whether federal law pre-empts a state law establishing a cause of action is a question of congressional intent." *Hawaiian Airlines, Inc. v. Norris*, 114 S. Ct. 2239, 2243 (1994); *see Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992); *see also CSX Transp., Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993) (stating that preemption "will not lie unless it is 'the clear and manifest purpose of Congress' ") (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

As the Supreme Court noted in Easterwood, evidence of preemptive purpose "is sought in the text and structure of the statute at issue." 113 S. Ct. at 1737. "If the statute contains an express pre-emption clause, the task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id.* Indeed, the existence of an express preemption clause supports an inference that Congress intended to limit the federal statute's preemptive scope to the express terms of the clause, although it "does not mean that the express clause entirely forecloses any possibility of implied preemption." *Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1488 (1995) (discussing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 (1992)). "Pre-emption . . .is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Fidelity Fed. Sav. & Loan Ass'n v. De La Cuesta*, 458 U.S. 141, 152-53 (1982) (quotations and citation omitted).

2.

We now apply these principles to the MDA. The MDA contains an express preemption provision, 21 U.S.C. § 360k(a), that provides:

> Except as provided in subsection (b) of this section [not relevant in this case], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

a.

Our first task is to determine whether the phrase "any requirement" encompasses state common law causes of action. Collagen submits that the Supreme Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 112 S. Ct. 2608 (1992), makes clear that Congress' preemption of state "requirements" encompasses common law causes of action. In *Cipollone*, the Court considered the scope of the preemption provision in section 5(b) of the Public Health Cigarette Smoking Act of 1969, which provided, in pertinent part:

> No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

See id. at 515, 112 S. Ct. at 2617 (quoting statute). A majority of the Justices agreed that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules." *Id.* at 521, 112 S. Ct. at 2620 (plurality op. of Stevens, J., joined by The Chief Justice, and White and O'Connor, JJ.); *see also id.* at 547, 112 S. Ct. at 2634 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part). These same Justices also agreed that the phrase "imposed under State law" included not only state statutes and regulations, but state common law as well. *Id.* at 2620 (plurality); *id.* at 2634 (Scalia, J., joined by Thomas, J., concurring in the judgment in part and dissenting in part).

Cipollone suggests that 21 U.S.C. § 360k(a)'s preemption

of state "requirement[s]" "different from, or in addition to," those of the MDA is broad enough to include state common law causes of action. This view is buttressed by an FDA regulation that interprets the statute's preemptive sweep as encompassing state requirements established by "statute, ordinance, regulation, or court decision." 21 C.F.R. § 808.1(b) (emphasis added). Indeed, these interpretive guides have led every circuit that has considered the question to conclude that 21 U.S.C. § 360k(a) preempts at least some common law causes of action.[3] Moreover, although we did not specifically discuss the scope of the "any requirement" clause, our decision in *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1332-34 (7th Cir.), *cert. denied*, 113 S. Ct. 327 (1992), which held various common law

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[3] *See, e.g., Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *2 (1st Cir. Aug. 14, 1995); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1323 & n.4 (3d Cir. 1995) ("[T]he term 'requirements' as used in § 360k encompasses state common law claims."), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir.) (relying upon *Cipollone*), *cert. denied*, 115 S. Ct. 429 (1994); *Feldt v. Mentor Corp.*, 61 F.3d 431, 433 n.2 (5th Cir. 1995); *Reeves v. Acromed Corp.*, 44 F.3d 300, 304 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1420-21 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Martello v. CIBA Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 991 (8th Cir. 1994) (holding that Congress' use of "requirement" evinced an intent for broad preemption of state tort laws); *Anguiano v. E.I. Du Pont de Nemours & Co.*, 44 F.3d 806, 809 (9th Cir. 1995) ("In promulgating the MDA, Congress expressly intended to preempt state tort law."); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995) ("Every circuit to consider the question agrees that common law actions are state requirements within the meaning of § 360k(a).").

causes of action against a manufacturer of intraocular lenses preempted by regulations promulgated under the MDA, certainly comports with the reasoning of these other circuits. Further, our decision in *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370-71 (7th Cir. 1993) relied explicitly upon *Cipollone* to hold that the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), which forbids states from imposing labeling requirements "in addition to or different from" federal requirements, preempted various common law claims. We see no reason to depart from these authorities, and we therefore make explicit that which was at least implicit in *Slater:* The phrase "any requirement" in 21 U.S.C. § 360k(a) is broad enough to include at least some common law causes of action within the statute's preemptive scope.

b.

i.

The Mitchells seek to avoid the result dictated by the precedents discussed above. They note that another provision of the MDA states that [c]ompliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account. 21 U.S.C. § 360h(d). The Mitchells submit that this portion of the MDA "saves" all common law causes of action from preemption. We cannot accept this contention. Although the existence of both a preemption provision and a savings clause in a federal statute indicates that Congress did not intend to preempt the field, *American Agric. Movement, Inc. v. Board of Trade*, 977 F.2d 1147, 1155 (7th Cir. 1992), "where the preemptive intent of Congress is clear, a general savings clause cannot supersede the specific preemption provision." *Lohr v. Medtronic, Inc.*, 56 F.3d

1335, 1343 (11th Cir. 1995) (analyzing 21 U.S.C. § 360h(d)) (citing *Morales*, 504 U.S. at 383-85). As we have noted above, the case law makes clear that Congress' reference to state "requirements" in preemption legislation evidences an intent to preempt at least some common law causes of action. Thus, we cannot agree that 21 U.S.C. § 360h(d) saves all such claims from preemption. At best, this provision saves some state law claims. *See Lohr*, 56 F.3d at 1343-44. However, nothing in the statute suggests which claims Congress meant to save. It is this question that we shall explore in the later pages of this opinion. At this point, in answer to the Mitchells' submission, it suffices to say that our holding today that not every state law cause of action is preempted under the MDA is consistent with the view that 21 U.S.C. § 360h(d) saves at least some claims from MDA preemption.

ii.

The Mitchells also invite our attention to an FDA regulation that provides that 21 U.S.C. § 360k(a):

> does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d). The Mitchells contend that this regulation saves all common law causes of action. They submit that the regulation constitutes a reasonable construction of the MDA and that it therefore is entitled to deference under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Under *Chevron*, the first step in interpreting

a federal statute is to determine whether its meaning is unambiguous; if Congress has spoken on the precise question at issue and its intent is clear "that is the end of the matter." *Id.* at 842. However, if the statute is silent or ambiguous with respect to the issue in question, we are obliged to defer to the interpretation provided by the agency charged with the responsibility of administering the statute, as long as the agency's interpretation is reasonable. *Id.* at 843. The FDA is charged with the responsibility of administering the MDA. 21 U.S.C. § 371(a). Accordingly, the FDA's interpretations of ambiguous MDA provisions are entitled to deference under *Chevron.*

The scope of the phrase "any requirement" in 21 U.S.C. § 360k(a) is not completely unambiguous;[4] we are therefore justified in looking to the regulation to ascertain its meaning. Nevertheless, we cannot accept the Mitchells' argument that 21 C.F.R. § 808.1(d)(1) saves all common law causes of action from preemption under the MDA. We believe that it is far more reasonable to read this regulation more narrowly. We note at the outset that the regulation does not speak to common law claims; its reference to requirements of "general applicability" is not to common law causes of action but to electrical codes and the U.C.C.--positive enactments of law. Indeed, section 808.1(d), listing various state requirements that are not preempted by the statute, is noticeably silent on the matter of state tort claims when read in its entirety. *See Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543 n.2 (3d Cir.) ("21 C.F.R. § 808.1(d) sets forth

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[4] *See, e.g., Lohr*, 56 F.3d at 1343-45 (concluding that meaning of "requirement" in § 360k(a) was not so clear and unambiguous as to preclude reliance upon FDA requirement, set forth in another portion of 21 C.F.R. § 808.1(d), that there must be specific MDA regulations or requirements relating to the medical device in question in order for state law claims to be preempted).

examples of state or local requirements that are not preempted by § 360k. Significantly, the list of requirements exempted from § 360k does not include state tort or common law claims."), *cert. denied*, 115 S. Ct. 429 (1994); *cf. Slater*, 961 F.2d at 1333-34 (concluding, in case not involving analysis of 21 C.F.R. § 808.1(d)(1), that MDA preempted some, but not all, state law causes of action of general applicability). Indeed, if we were to give 21 C.F.R. § 808.1(d) the breadth which the Mitchells urge that we give it, we would contradict squarely the manifest intent of the statute which, as we have already noted, clearly evidences a congressional intent to preempt some common law causes of action. *Cipollone* teaches that, when Congress uses phraseology almost identical to that used in 21 U.S.C. § 360k(a), it evidences an intent to preempt at least some common law causes of action. Our decision in *Shaw* confirms this view. *See Shaw*, 994 F.2d at 370-71. Under these circumstances, we would be obliged to give no deference to such an expansive reading of the regulation. "The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent." *Chevron*, 467 U.S. at 843 n.9.

Accordingly, we cannot accept the view that 21 U.S.C. § 360k(a) may reasonably be read as failing to encompass *any* common law cause of action of general applicability. *Cf. Michael v. Shiley, Inc.*, 46 F.3d 1316, 1323 n.4 (3d Cir. 1995) (noting, without expressing a view on the validity of the regulation, that "[d]espite the reference in 21 C.F.R. § 808.1(d)(1) to laws of general applicability, we hold that the statutory language of § 360k preempts Michael's claims for breach of the implied warranties of merchantability and fitness[.]"), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June

2, 1995) (No. 94-1971).[5]

3.

Having determined that 21 U.S.C. § 360k(a) is broad enough to preempt at least some common law causes of action, we now consider the precise scope of this preemption provision. Initially, we note that the language in 21 U.S.C. § 360k(a)(2) providing that the state "requirements" must "relate[ ] to the safety or effectiveness of the device or to any other matter in a requirement applicable to the device" under the MDA does not cabin significantly the preemptive sweep of the statute. In *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995), the Supreme Court recently emphasized that, when Congress uses the phrase "relates to" in a preemption provision, the phrase should be construed broadly. *See id.* at 821 (defining the phrase "relates to" as "having a connection with or reference to") (citing *Morales v. Trans World Airlines*, 112 S. Ct. 2031, 2037 (1992); *Shaw v. Delta Airlines*, 463 U.S. 85, 97 (1983)). We must also consider the breadth of the language in § 360k(a). It expressly preempts claims relating not only to "safety and effectiveness," but also to "any other matter included in a requirement," 21 U.S.C. § 360k (a)(2) (emphasis added). The section therefore encompasses state law claims that add requirements "different from, or in addition to," any requirement set forth in the MDA. *See Michael*, 46 F.3d at 1330-31; *cf. Cipollone*, 505 U.S. at 523, 112 S. Ct. at 2621 (plurality op.)

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[5] The Eleventh Circuit's decision in Lohr, which found the scope of § 360k(a) ambiguous for purposes of deferring to another portion of 21 C.F.R. § 808.1(d), does not conflict with this reasoning; indeed, the Eleventh Circuit specifically held that some types of common law claims of general applicability were preempted by the MDA. *See* 56 F.3d at 1350-51.

(focusing upon whether legal duty serving as predicate for state law action was based upon smoking and health where preemptive sweep of statute was limited to state laws based upon smoking and health).

The Mitchells' chief contention, however, does not concern whether their state law claims "relate to" some MDA requirement applicable to Zyderm; rather it concerns whether such a "requirement" exists. The Mitchells focus upon a portion of 21 C.F.R. § 808.1(d) that provides:

> [S]tate or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d). This regulation makes clear, the Mitchells contend, that common law causes of action survive preemption unless the FDA has established "specific counterpart regulations" or "other specific requirements" for the medical device in question. They submit that, because no such "regulations" or "requirements" exist with respect to Zyderm, none of their common law causes of action are preempted.

In response, Collagen does not challenge the validity of the FDA regulation. *Cf. Lohr*, 56 F.3d at 1343-45 (holding that this portion of 21 C.F.R. § 808.1(d) is entitled to deference). Rather, it contends that the detailed premarket approval process constitutes a "specific requirement" applicable to Zyderm and other Class III medical devices. Therefore, Collagen contends, any state laws that seek to add requirements "different from, or in addition to," the premarket approval process are preempted

under the MDA.

Although the Mitchells correctly note that the FDA has issued no regulation or requirement relating exclusively to Zyderm, we cannot accept their argument. Our colleagues in the Eleventh Circuit recently explained the fallacy inherent in the argument that the FDA's premarket approval process does not constitute a "specific requirement" for purposes of 21 C.F.R. § 808.1(d):

> The most natural reading of the FDA's "specific requirements" language requires specificity in the nature of the requirements, not in their applicability to designated devices. The "applicable to a particular device" language, mirroring the statute, requires a court to ask whether the requirements in question apply to the device in question. . . .
>
> Construing the FDA's preemption regulations to require device specificity also contradicts the structure of the Act. Under the MDA, Class III devices are subject to the highest level of scrutiny through the PMA process. . . . Yet the PMA procedure's "requirements" under the MDA are not device-specific. Instead, the PMA process requires manufacturers to submit to an approval process standardized for all Class III devices. . . . It would be anomalous for the MDA to preempt certain claims which conflict with device-specific requirements placed on Class II devices . . . but not preempt claims against devices subject to the MDA's most rigorous, albeit non-device-specific, procedures.

Lohr, 56 F.3d at 1345-46 (internal footnotes and citations omitted). We agree with this reasoning and conclude that the premarket approval process constitutes a "specific requirement" for purposes of 21 C.F.R. § 808.1(d) and 21 U.S.C. § 360k(a).

In doing so, we align ourselves with the majority of circuits to have considered this question.[6]

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[6] *See, e.g., Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir. 1995) (noting that premarket approval procedures present "specific requirements applicable to a particular device under the act"), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971); *Martello v. CIBA Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994) ("The premarket approval process is a specific requirement for a device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d)."), *cert. denied*, 115 S. Ct. 2614 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 & n.3, 1424 & n.8 (5th Cir.) (stating, in case involving Zyderm, that the "Class III PMA process" is a "specific requirement" for purposes of § 808.1(d)), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.) (op. of Torruella, J., joined by Aldrich and Campbell, JJ.) ("FDA regulations provide that preemption does not apply when the FDA has issued no regulations or other requirements specific to the particular device. . . In this case, it is clear that the FDA has imposed requirements on Zyderm related to labeling, design, manufacturing and other aspects of the device pursuant to the MDA scheme.") (emphasis added), *cert. denied*, 114 S. Ct. 84 (1993); *see also Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1346 (11th Cir. 1995) (noting agreement with rationale that PMA process constitutes a "specific requirement" for purposes of § 808.1(d) in case involving Class III device exempted from the PMA process); *cf. Feldt v. Mentor Corp.*, 61 F.3d 431, 436 & n.5 (5th Cir. 1995) (noting, in case involving Class III device not subject to PMA process, that FDA requirements need not be device-specific) (citing *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989) (Class II device case)). But *cf. La Montagne v. E.I. Du Pont de Nemours & Co.*, 41 F.3d 846, 855 (2d Cir. 1994) (rejecting MDA preemption argument "substantially for the reasons stated by the district court in its opinion"; district court, 834 F. Supp. 576, 582-85 (D. Conn. 1993), concluded that no specific requirements existed with respect to a device that ultimately had been classified as a Class III device, but which had not been subjected to PMA process at the time it was implanted into the plaintiff).

4.

We now must analyze each of the Mitchells' claims against Collagen to determine whether they would add requirements "different from, or in addition to," the PMA process or other FDA requirements and therefore be preempted. Collagen submits that all of the Mitchells' claims are preempted. The Mitchells contend that recent court decisions have made clear that at least their fraud, misrepresentation, and breach of warranty claims survive preemption. In response, Collagen argues that the Mitchells may not benefit from these decisions because they have not made a sufficient summary judgment record.

a. Strict Liability & Negligence Claims

At the outset, we note that the Mitchells do not contend

The Ninth Circuit's decision in *Anguiano v. E.I. Du Pont de Nemours & Co.*, 44 F.3d 806 (9th Cir. 1995), has been cited as adopting the rule advocated by the Mitchells in this case. *See Lohr*, 56 F.3d at 1346. *Anguiano* involved a Class II medical device that, by definition, was not subject to the PMA process. Although the court in *Anguiano* did state that "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device," 44 F.3d at 809 (quotations and citations omitted), the court later noted that the "argument that the MDA regulatory framework preempts state law, even absent specific provisions, applies only to Class III devices, not Class II devices." *Id.* at 810. The latter statement suggests that the Ninth Circuit's position comports with the majority of other circuits, at least with respect to Class III devices. Indeed, the court in *Anguiano* cited to decisions from the First and Fifth Circuits to support the statement referred to by *Lohr*, yet, as is indicated above, the First and Fifth Circuits have concluded that the premarket approval process constitutes a "specific requirement" applicable to "particular device[s]" for purposes of 21 C.F.R. § 808.1(d).

seriously that their strict liability and negligence claims would neither "establish [n]or continue in effect" a requirement "different from, or in addition to," the requirements involved in the PMA process. Read generously, their brief addresses these claims only in its section presenting the argument that 21 C.F.R. § 808.1(d) saves all common law causes of action from preemption. *See* Appellant's Br. at 15-21. As we noted above, that argument is flawed.

In any event, these claims are preempted by the MDA. The Mitchells' strict liability claim consists of allegations that Zyderm was "an unreasonably dangerous product" and that Collagen "knew or in the course of reasonable care should have known" that Zyderm "was unreasonably dangerous and had the potential for causing serious immunological and/or autoimmune reactions, damage and injuries when injected into humans for its intended use and purpose." *See* R.1, Ex.A at 2-3, Count I, paras. 7, 9. The complaint alleges the following negligence claims: "inadequate warnings accompanied" Zyderm, *id.* at 2, Count I, para. 8, and "Collagen Corporation was negligent in the design, testing, approval, manufacturing, marketing and sale" of Zyderm, *id.* at 5, Count IV, para. 2.

We agree with several other circuits which have considered the issue that, with respect to a Class III device that has undergone the PMA process, such claims are preempted because they undoubtedly would add requirements "different from, or in addition to," those set forth in the MDA.[7] "FDA

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[7] *See, e.g., Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir. 1995) (citing *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 543-44 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994), for the proposition that "state law negligence and strict product liability claims are pre-empted under § 360k on account of the potential conflict with FDA labeling, design, and manufacturing requirements"), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971); *Martello v. CIBA Vision*

Corp., 42 F.3d 1167, 1169 (8th Cir. 1994) (strict products liability and negligent instruction, labeling, warning, and testing claims), *cert. denied*, 115 S. Ct. 2614 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 & n.5 (5th Cir.) (failure to warn, defective design, and defective manufacturing claims), *cert. denied*, 114 S. Ct. 86 (1993); *King v. Collagen Corp.*, 983 F.2d 1130, 1135-36 (1st Cir. 1993) (op. of Torruella, J., joined by Aldrich and Campbell, JJ.) (strict liability and negligent design, manufacturing, marketing, and sales claims), *cert. denied*, 114 S. Ct. 84 (1993); *see also Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *6 (1st Cir. Aug. 14, 1995) (adopting analysis of district court, which held claims for negligent design, development, and manufacture preempted); *Lewis v. Intermedics Intraocular, Inc.*, 56 F.3d 703, 708 (5th Cir. 1995) (noting, in intraocular lens case, "[i]f plaintiffs' products liability claims for recovery due to the lenses' dangers are preempted, then it would seem ridiculous to say that a claim for failure to warn about these dangers could survive"); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18-19 (1st Cir. 1994) (negligent failure to warn and negligent manufacturing claims preempted for Class III device not subject to PMA process); *cf. Feldt v. Mentor Corp.*, 61 F.3d 431, 436 & n.6 (5th Cir. 1995) (holding, with respect to Class III device not subject to PMA process, that negligent marketing and inadequate warning claims were preempted, but defective design claim was not preempted because no FDA design requirement existed); *Lohr*, 56 F.3d at 1347-52 (11th Cir. 1995) (holding, with respect to Class III device that had not undergone PMA process, that negligent design and strict liability claims were not preempted, but that MDA's good manufacturing regulations, warning, and labeling requirements nonetheless preempted negligent manufacture and negligent failure to warn claims).

In *Reeves v. Acromed Corp.*, 44 F.3d 300, 304-05 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995), the Fifth Circuit held that failure to warn claims were preempted by the MDA with respect to a Class III device not subject to the PMA process. The opinion indicates that various negligent design and manufacturing defect claims went to the jury during the district court proceedings, but does not comment upon

approval of a premarket application shows the FDA has reviewed a device's testing, design specifications, intended use, manufacturing method, performance standard, and labelling, . . . and decided the device is safe and effective." *Martello v. CIBA Vision Corp.*, 42 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995) (citing 21 U.S.C. §§ 360c(a)(2), 360e(c)(1)); *see also Ministry of Health, Province of Ontario, Can. v. Shiley, Inc.*, 858 F. Supp. 1426, 1438-39 (C.D. Cal. 1994) (stating that "a finding of negligence would mean implicitly finding that the FDA approval was not good enough," and that a successful strict liability claim would require a court to hold that the product was unsafe and dangerous "in opposition to the contrary determination made by the FDA"); *cf. Slater*, 961 F.2d at 1332-33 (indicating that claims for inadequate testing, defective design, and failure to warn were preempted in case involving device not subject to PMA process).

b. Mislabeling, Misbranding, and Adulteration

i.

The Mitchells' complaint also alleged that Zyderm was a "mislabeled and/or adulterated product." R.1, Ex.A at 5, Count IV, para. 2. To the extent that this allegation charges that Zyderm, despite conformity to the FDA's premarket approval process, was mislabeled, misbranded, or adulterated, the Mitchells' claim would be preempted for the reasons discussed in the previous subsection. In essence, the claim would seek to add requirements "different from, or in addition to," those established through the FDA's premarket approval process. *See*

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whether such claims are or are not preempted under the MDA. *See id.* at 307-08.

Martello, 42 F.3d at 1169; *see also Slater*, 961 F.2d at 1332-34; *cf.* 21 C.F.R. § 808.1(d)(6)(ii) (noting that state requirements prohibiting manufacture of misbranded and adulterated devices are preempted to the extent they establish substantive requirements "different from, or in addition to, a Federal requirement established under the act").

On the other hand, it is possible to view the Mitchells' claim as alleging that Zyderm was mislabeled or adulterated because Collagen failed to meet the labeling and purity standards established by the PMA process. Various circuits have suggested that this is a distinction without a difference--such claims are nonetheless preempted.[8] A principal tenet of these decisions is that a court applying state law to ensure compliance with the federal standards may get the federal standards wrong and, therefore, end up imposing a requirement "different from or in addition to" the requirements established under the MDA.

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[8] *See, e.g., Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *4-6 (1st Cir. Aug. 14, 1995) (analyzing fraud against the FDA claim, but reasoning generally that any state law suit based upon a claim that the defendant had failed to comply with the MDA would be preempted because "if state courts erred in their application of the MDA, they would effectively be imposing requirements 'different from, or in addition to' those imposed by federal law"); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1343 (11th Cir. 1995) ("[P]reemption under the MDA cannot be defeated by a common-law suit alleging a violation of the statutory standards."); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir.) (noting, with respect to intraocular lens device, that adulteration claim based on failure to meet FDA standards was preempted; "[t]he FDA can determine an investigational device to be adulterated if requirements under [applicable regulations] are not complied with"), *cert. denied*, 115 S. Ct. 429 (1994); *cf. Reeves v. Acromed Corp.*, 44 F.3d 300, 307 & n.4 (5th Cir.) ("We . . . decline . . . to create an unwieldy exception . . . in cases where manufacturers . . . violate FDA regulations."), *cert. denied*, 115 S. Ct. 2251 (1995).

See Talbott v. C.R. Bard, Inc., No. 94-1951, 1995 WL 470265, at *4 (1st Cir. Aug. 14, 1995).

When the claim is that a particular product is adulterated because it does not comply with standards explicitly established by the FDA or that a particular label does not comply with standards explicitly established by the FDA, the correctness of this approach is not self-evident. In such circumstances, the existence of the FDA-approved paradigm appears to ensure that state law cannot impose requirements "different from or in addition to" federal law. The Eighth Circuit has stated that, "when a statute only preempts state requirements that are different from or in addition to those imposed by federal law, plaintiffs may still recover under state tort law when defendants fail to comply with the federal requirements." *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 993 (8th Cir. 1994); *see also Martello*, 42 F.3d at 1169 ("Martello did not claim the AOSEPT he used did not comply with federal regulations[.]"); *cf. Slater*, 961 F.2d at 1334 (commenting that the scope of MDA preemption is "limited to efforts by states to impose sanctions for compliance with federal regulations[.]"). In the absence of more explicit legislative or regulatory direction,[9] we hesitate to say, therefore, that an adulteration claim based on a product's failure to meet PMA standards-- standards that have been explicitly set forth by the FDA--does not survive MDA preemption. Such a claim seeks merely to enforce the federal standard, not to add requirements "different from, or in addition to," it.

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[9] We note that the existing regulations, albeit laconic, presently lend some support for the view that an adulteration claim based on a product's failure to meet PMA standards survives MDA preemption. See 21 C.F.R. § 808.1(d)(2) (stating that state or local requirements "equal to, or substantially identical to," federal requirements imposed under the MDA are not preempted).

ii.

The Mitchells' summary judgment filings suggest that their mislabeling and misbranding claims were directed at the labeling and branding of Zyderm generally, *see, e.g.*, R.12 at 13, and therefore were preempted for the reasons discussed above. Their adulteration claim seems to have concerned Zyderm's alleged failure to meet the performance standards set forth in its PMA. *See id.* at 14. Nevertheless, even construing the Mitchells' claim in this fashion, we hold that the district court did not err in granting Collagen summary judgment because Collagen established that there was no genuine issue of material fact that Zyderm was unadulterated. In its statement of material facts "in which there [was] no genuine issue," Collagen contended that "[t]here is no evidence to support Barbara Mitchell's claim for mislabeling and/or misbranding and/or adulteration." R.5 at 3 para. 18. Collagen supported this claim with an affidavit from Ross Erickson, Collagen's Vice President for Regulatory Affairs and Quality Assurance. Mr. Erickson asseverated that:

> Prior to 1988, and during that period of time in 1988 when plaintiff Barbara Mitchell was being treated with Zyderm and Zyplast, neither Zyderm nor Zyplast was ever determined by the FDA to be either mislabeled or adulterated. Any such citation would be in the records for which I have primary responsibility.

R.3, Aff. of R. Erickson para. F. In response to these submissions, the Mitchells stated that they "would dispute the veracity and/or materiality of Defendant Collagen Corporation's alleged material facts, in particular as to allegation number[ ] 18." R.13 at 2 para. 3. However, the Mitchells introduced no affidavits, depositions, or other materials to counter the Erickson affidavit.

Although the Mitchells contended at oral argument, as well

as in their brief, that such submissions were unnecessary because the district court was ruling on purely legal issues, the Record makes clear that Collagen argued in the district court not only that adulteration claims should be preempted per se, but also that no genuine issue of material fact existed with respect to the Mitchells' adulteration claim. Indeed, the district court explicitly ruled that Collagen alternatively was entitled to summary judgment on the adulteration claim because the Mitchells had "pointed to no evidence of adulteration upon which they could go to a jury." 870 F. Supp. at 897. The Mitchells' failure to come forward with any evidence in response to Collagen's submission that there was no genuine issue of material fact with respect to the adulteration claim entitled Collagen to summary judgment. *See Doe v. R.R. Donnelley & Sons Co.*, 42 F.3d 439, 443 (7th Cir. 1994). "[S]ummary judgment must be entered 'against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.' " *Id.* (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

c. Fraud and Misrepresentation

The Mitchells' complaint raised two distinct claims for fraud and misrepresentation:

> Collagen Corporation[ ] procured approval to market and sell the named products through fraud and misrepresentation. Defendant, Collagen Corporation[,] markets and sells the named products through fraud and misrepresentations, by act and/or omission.

R.1, Ex.A at 5, Count IV, para. 2. The allegation in the first sentence constitutes a claim that Collagen defrauded the FDA to obtain approval to sell Zyderm; the second sentence alleges

that Collagen committed fraud in the course of selling its product.

i.

The Mitchells' "fraud on the FDA" claim is preempted. As the Third Circuit recently noted, such claims seek to encourage the district court to review the PMA application [the defendant] submitted to the FDA. This inquiry could ultimately require that a court determine whether the information . . . submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations. In sum, this claim requires a court, applying state law, to perform the same functions initially entrusted to the FDA. *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1329 (3d Cir. 1995), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971). We agree with the Third Circuit that 21 U.S.C. § 360k(a) "does not permit such a searching state inquiry into the inner workings of FDA procedures." *Id.*; *accord Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *3 (1st Cir. Aug. 14, 1995); *Reeves*, 44 F.3d at 306. "Surely, where the FDA was authorized to render the expert decision on Collagen's use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions. Further, if the court erred, and incorrectly posited the effect on the FDA's use and labeling decision, this would impose a state requirement 'which is different from, or in addition to, any requirement applicable . . . to the device.' " *King*, 983 F.2d at 1140 (Aldrich and Campbell, JJ., concurring) (quoting 21 U.S.C. § 360k(a)).

ii.

With respect to the Mitchells' other fraud claim, we note

first that, in the district court, the Mitchells did not specify the nature of Collagen's alleged fraudulent statements or misrepresentations. *Cf.* Fed. R. Civ. P. 9(b). The district court viewed their claim as one alleging that Collagen's packaging and labeling were misleading; in other words, the court considered the claim as equivalent to the misbranding and mislabeling claims. *See* 870 F. Supp. at 897. Therefore, for the reasons set forth in our earlier discussion of mislabeling, misbranding, and adulteration, the district court concluded correctly that the Mitchells' fraud and misrepresentation claims were preempted. *See, e.g., Michael,* 46 F.3d at 1331 (indicating that fraud claims would be preempted to the extent that they alleged fraudulent labeling); *see also* 21 U.S.C. § 360e(d)(2)(D) (requiring FDA to deny premarket approval of labeling that is "false or misleading in any particular").

On appeal, the Mitchells now have characterized their claim as one alleging that Collagen's "advertising and promotional materials" were fraudulent. *See* Reply Br. at 3. This belated refinement of their claim seeks to benefit from the Third Circuit's decision in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995), *petition for cert. filed,* 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971), which held that fraudulent advertising claims were not preempted under the MDA. The Third Circuit reasoned that there were no requirements in the MDA that governed the promotional materials at issue in the case. Consequently, the court held that a state law fraud claim would not add any requirement "different from, or in addition to," a requirement under the MDA. *See id.* at 1330.

Even were we to give the Mitchells the benefit of the doubt and construe their claim with the specificity they have added on appeal, their claim nonetheless would fail. Unlike the defendant in Michael, Collagen, through the exhibits attached to the affidavit of Ross Erickson, established that the FDA had placed restrictions on Collagen's advertising and promotional

materials.[10] The Mitchells did not introduce affidavits, depositions, or other materials either to rebut Collagen's submissions or to demonstrate that there were genuine issues with respect to other promotional materials. Accordingly, summary judgment was proper even if the Mitchells' claim could be construed as applying to fraud and misrepresentation with respect to Collagen's advertising and promotional materials. *See R.R. Donnelley & Sons Co.*, 42 F.3d at 443; *see also Meredith v. Allsteel, Inc.*, 11 F.3d 1354, 1358 (7th Cir. 1993) ("We may affirm the district court's grant of summary judgment on an alternative basis, as long as that basis finds support in the record.").

d. Warranty

The Mitchells' complaint raised the following warranty claim: "At all material times, Defendant, Collagen Corporation . . . warranted and represented to Plaintiff, Barbara Mitchell, that [Zyderm was] safe for [its] intended use and purpose." R.1, Ex.A at 2, Count I, para. 5. Before the district court, the Mitchells neither specified what warranties were at issue nor what statements of warranty Collagen allegedly provided.

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[10] *See, e.g.*, R.6, Ex.13 at 2 (Dec. 1981 letter from Acting Director of FDA Bureau of Medical Devices approving supplemental premarket application and indicating that "[n]o advertisement for this device shall recommend or imply that the device may be used for any use that is not mentioned in the approved labeling for the device. All written promotional material shall state the indications, contraindications, warnings, precautions and adverse effects of the device"); R.6, Ex.26 (Nov. 1983 letter ordering Collagen to "refrain from any reference to 'FDA approval' or 'marketing clearance by the FDA' in all promotional material or labeling for Zyderm").

i. Implied Warranty

Various circuits have held that implied warranty claims are preempted with respect to devices that have undergone the PMA process.[11] These courts have emphasized that such claims, as they relate to manufacturing or design problems, "by necessity depend[ ] upon the accepted standards for the design and manufacture of products" in the state whose law provides the cause of action--standards that "may deviate from the FDA's determinations in the PMA process or from the FDA's 'good manufacturing practices.' " *Michael*, 46 F.3d at 1325; *see also Mendes*, 18 F.3d at 19. Likewise, claims based upon inadequate warnings seek to add requirements "different from, or in addition to," the labeling approved by the FDA. *Mendes*, 18 F.3d at 18. In sum, "[a]s an implied warranty is a requirement upon a product that arises exclusively from the operation of state contract law, [implied warranty] claim[s] [are] preempted expressly by the MDA." *King*, 983 F.2d at 1135 (op. of

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[11] *See, e.g., Michael*, 46 F.3d at 1324-25; *Martello v. CIBA Vision Corp.*, 42 F.3d at 1168-69; *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir.) (op. of Torruella, J., joined by Aldrich and Campbell, JJ.), *cert. denied*, 114 S. Ct. 84 (1993); *see also Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *6 (1st Cir. Aug. 14, 1995) (adopting analysis of district court, which held implied warranty claim preempted); *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 18-19 (1st Cir. 1994) (finding implied warranty claim preempted for Class III device not subject to PMA process); *Duncan v. Iolab Corp.*, 12 F.3d 194, 195 (11th Cir. 1994) (per curiam) (same for intraocular lens); *cf. Feldt v. Mentor Corp.*, 61 F.3d 431, 437 & n.9 (5th Cir. 1995) (holding that implied warranty claim relating to defective design was not preempted with respect to Class III device that had not undergone PMA process and distinguishing Michael on the ground that the device at issue in Michael had undergone the PMA process).

Torruella, J., joined by Aldrich and Campbell, JJ.). We agree with the analysis of these other circuits, and therefore hold that the Mitchells' claim is preempted to the extent it alleges violation of an implied warranty relating to the design, manufacturing, or labeling of Zyderm.

ii. Express Warranty

As the Mitchells note on appeal, there is significant authority for the proposition that express warranty claims are not preempted by the MDA. The Third Circuit stated in *Michael v. Shiley, Inc.*, that [e]xpress warranties arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law. . . . The parties to a contract, not the state, define the substantive obligations of the contract and hence any express warranties. While the state provides for the enforcement of the parties' bargain, it does not define each party's duties. 46 F.3d at 1325. The court went on to note that its reasoning comported with the Supreme Court's recent decision in *American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995). In *Wolens*, the Court considered the scope of the preemption provision in the Airline Deregulation Act of 1978, which provided, in pertinent part:

> [N]o State . . . shall enact or enforce any law, rule, regulation, standard, or other provision having the force and effect of law relating to rates, routes, or services of any air carrier.

See 115 S. Ct. at 821 (quoting 49 U.S.C. § 1305(a)(1)). The Court concluded that the statute did not preempt suits "seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings." *Id.* at 824. Focusing upon the phrase "enact or enforce" in the statutory scheme, the Court emphasized that "terms and conditions airlines offer and

passengers accept are privately ordered obligations and thus do not amount to a State's 'enact[ment] or enforce[ment] [of] any law[.]" *Id.* (internal quotation and citation omitted) (citing *Cipollone*, 112 S. Ct. at 2608 (plurality op.) ("[A] common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a 'requirement imposed under State law[.]' ")). The Court in *Wolens* concluded, "[a] remedy confined to a contract's terms simply holds parties to their agreements[.]" 115 S. Ct. at 824.

The operative phrase in the preemption provision at issue in *Wolens*, "enact and enforce," differs from the MDA's command that states may not "establish or continue in effect" any requirements different from or in addition to those set forth in the MDA. Compare 49 U.S.C. § 1305(a)(1) with 21 U.S.C. § 360k(a). Nevertheless, the reasoning in *Michael* does find significant support both in *Wolens* and in the portion of *Cipollone* quoted above. Moreover, we note that the Third Circuit also reasoned that, with respect to the MDA in particular, enforcement of an express warranty would not seek to add requirements "different from, or in addition to," those set forth in the MDA, but rather, would "enforce the very language which the FDA approved" on the particular label at issue. *See* 46 F.3d at 1328. We agree.

Collagen seeks to counter the persuasiveness of *Michael* by noting that other circuits disagree. Collagen principally cites the First Circuit's decision in *King*. However, although Judge Torruella's separate opinion in *King* supports Collagen's argument that express warranty claims are preempted, *see* 983 F.2d at 1135 (op. of Torruella, J.), a majority in *King* declined to address the express warranty issue and suggested that "[e]xpress warranty might have created a problem for the defense of preemption." *Id.* at 1137 & n.3 (Aldrich and Campbell, JJ., concurring) (citing *Cipollone*, 112 S. Ct. at 2622-23). Thus, contrary to Collagen's submission, *King* may

not stand for the proposition that express warranty claims are preempted under the MDA; in turn, those decisions cited by Collagen that rely upon *King* for this proposition without additional analysis are not persuasive. *See, e.g., Martello,* 42 F.3d at 1169. But see *Talbott v. C.R. Bard, Inc.*, No. 94-1951, 1995 WL 470265, at *6 (1st Cir. Aug. 14, 1995) (Campbell, J.) (affirming district court's dismissal of express warranty claim and stating that the Third Circuit's express warranty analysis in *Michael* "appears to be inconsistent with this circuit's approach as set forth in *King,* 983 F.2d at 1135," but not commenting on footnote 3 of Judge Aldrich's opinion in *King*). Accordingly, we hold, consistent with Michael, that the MDA does not preempt express warranty claims.

Once again, however, the Mitchells' summary judgment filings prevent them from benefitting from this analysis. As we noted above, the Mitchells never specified in the district court whether their claim was based upon implied or express warranties. Likewise, the Mitchells never pointed to any express warranty that Collagen allegedly violated. In response to Collagen's submission that there was no genuine issue of material fact with respect to their complaint against Collagen, the Mitchells introduced no affidavits, depositions, documents, or other evidence creating a genuine issue of fact as to the existence of any express warranty provided by Collagen. Accordingly, we must hold that the Mitchells failed to meet their burden at the summary judgment stage and that, to the extent they raised an express warranty claim in their complaint, summary judgment was proper even though such claims are not preempted by the MDA. *See R.R. Donnelley & Sons Co.*, 42 F.3d at 443; *see also Meredith,* 11 F.3d at 1358 ("We may affirm the district court's grant of summary judgment on an alternative basis, as long as that basis finds support in the record.").

Conclusion

For the foregoing reasons, the decision of the district court is affirmed.

AFFIRMED

SUPREME COURT OF THE UNITED STATES

Barbara Mitchell, *et vir*

v.

Collagen Corporation

No. 95-1323

The petition for a writ of certiorari is granted. The judgment is vacated and the case is remanded to the United States Court of Appeals for the Seventh Circuit for further consideration in light of *Medtronic, Inc. v. Lohr,* 518 U.S. --- (1996).